INSTRUCTIONS FOR USE

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

INDICATIONS FOR USE

The *LATERA Absorbable Nasal Implant System* 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, as it may result in compromised device performance and risk improper sterilization and cross-contamination.
- 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 *Implant* is not intended to replace normal healthy bone or cartilage.
- Subsequent infection may require *Implant* removal.
- Do not expose the *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, minor cosmetic changes, 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 Implant, Delivery Device, and Implant Positioning Guide* are sterilized with electron beam radiation. Do not use if the packages are open or damaged.
- **IMPLANT STORAGE:** Store in a cool, dry location at or below 30°C.
- **DELIVERY DEVICE STORAGE:** Store in a cool dry place
- **SINGLE USE:** The *LATERA Absorbable Nasal Implant System* is intended for single patient use only. The *Delivery Device* may be used to deliver multiple *Implants* to a single patient in a single clinical setting. Do NOT re-sterilize and/or reuse.

DEVICE DESCRIPTION

The *LATERA Absorbable Nasal Implant System* is composed of the *Implant, Delivery Device, and Implant Positioning Guide*. The *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 is available in two lengths, 20mm and 24mm, 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. *Implant* size is noted on the lid. The *Implant* is depicted in **Figure 1** below.

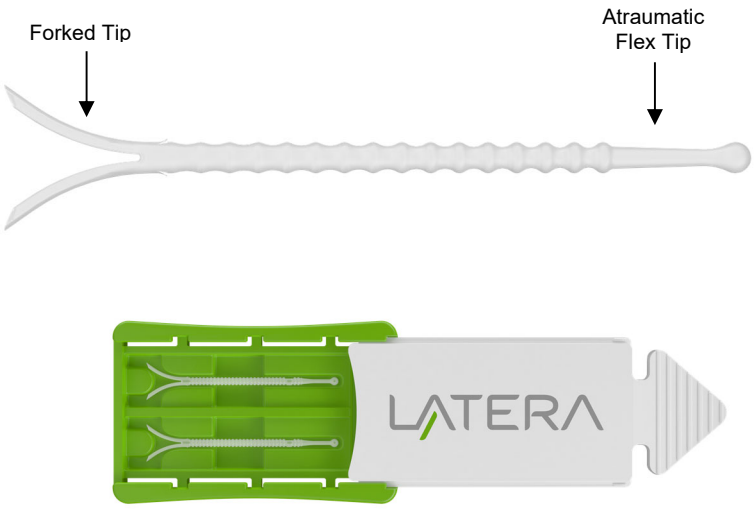


Figure 1: LATERA Absorbable Nasal *Implant* and Packaging

NOTE: Images representative; *Implant* available in two overall lengths of 20mm and 24mm

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 compatible implant size is indicated on the top of the delivery device handle. The inner shaft includes an implant loading port which enables the loading of the *Implant* and 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 delivery cannula has a beveled tip which enables piercing and advancement through tissue and a reference mark (7-9mm from the cannula tip) to aid in determining cannula insertion depth 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. Each *Implant* length (20mm, 24mm) is compatible with the *Delivery Device* packaged with the *Implants*. The *Delivery Device* and the *Implant Positioning Guide* are shown in **Figure 2** below.

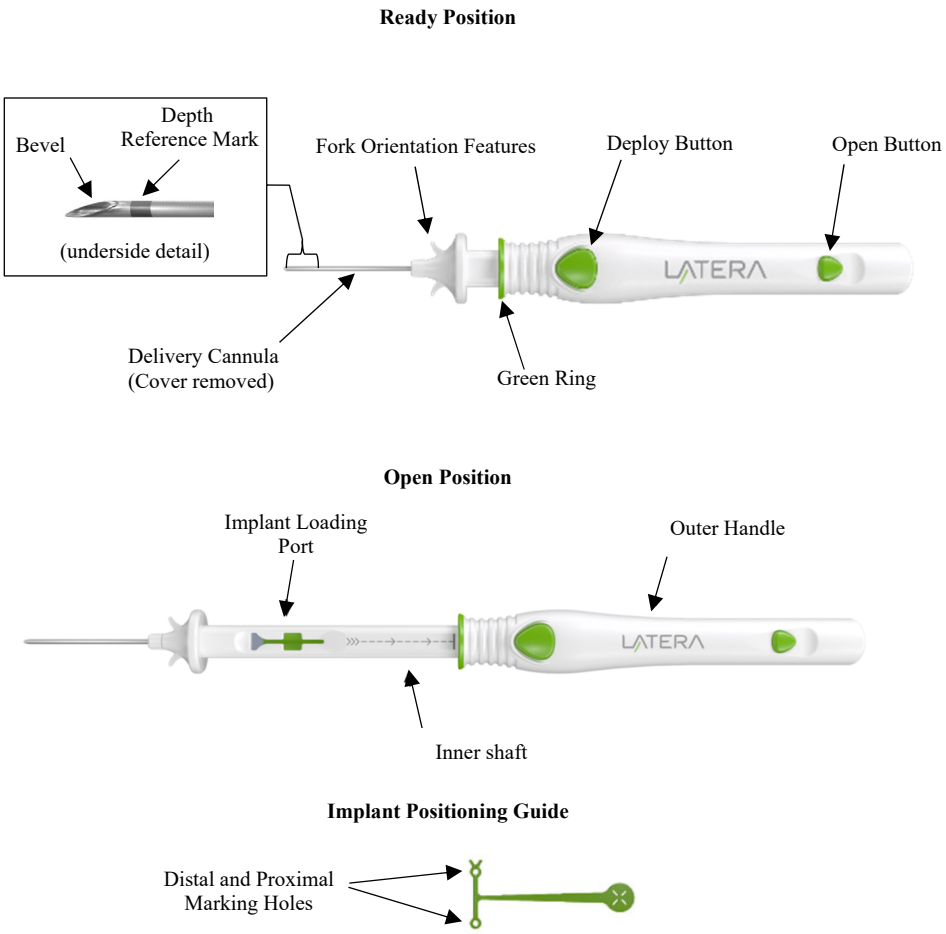


Figure 2: *Delivery Device* and *Implant Positioning Guide*

*NOTE: Images representative. *Implant* system size will be printed on the *Delivery Device*.

For proper insertion:

- The 20mm *Implant* is compatible with the 20mm *Delivery Device* and 20mm *Implant Positioning Guide.*
- The 24mm *Implant* is compatible with the 24mm *Delivery Device* and 24mm *Implant Positioning Guide.*

INSTRUCTIONS FOR USE

Implant Target Location and Device Preparation:

1. Select an appropriate *Implant* length. The *Implant* is available in two lengths, 20mm and 24mm. Nasal anatomy (i.e. nose size, length of maxilla/nasal bone, alar crease position, etc.) should be considered in selecting an *Implant* length. A ruler may be used to help determine the desired size.
2. Prepare the site for implantation using standard surgical procedures (e.g. cleaning, disinfection, anesthetic, etc.).
3. Identify the target *Implant* location and cannula insertion trajectory prior to implantation. 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. The proximal tip of the *Implant* should be placed cephalic to the supra-alar crease as shown in **Figure 3**.

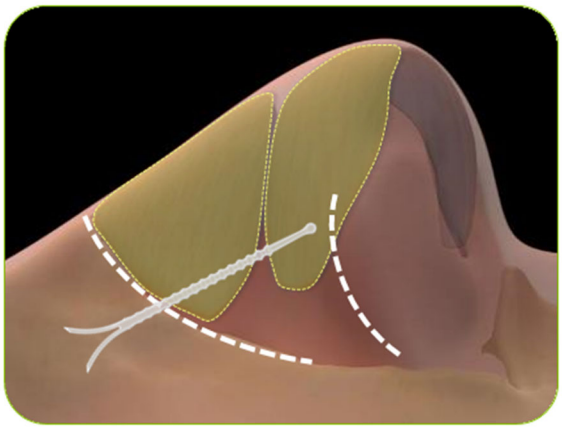


Figure 3: Example Implant location showing support of upper and lower lateral cartilage, the position of *Implant* forks across maxilla bone to cartilage transition (left most dashed line) and the position of the proximal tip cephalic to the supra alar crease (right most dashed line).

4. Use the *Implant Positioning Guide* and standard surgical pen to mark the surgical trajectory as shown in **Figure 4**. 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.

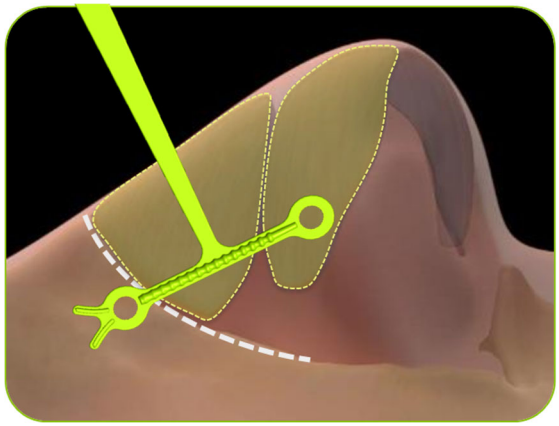


Figure 4: *Implant Positioning Guide* superimposed on upper and lower lateral cartilage

5. 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. 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.
6. Use sterile surgical forceps to 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

7. Slowly advance the outer handle towards the delivery cannula end until the outer handle locks into the ready position. There will be a small space between the outer handle and cannula as shown in **Figure 6b**. 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 **Figures 6a** and **6b** 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 device preparation process from Step 5.

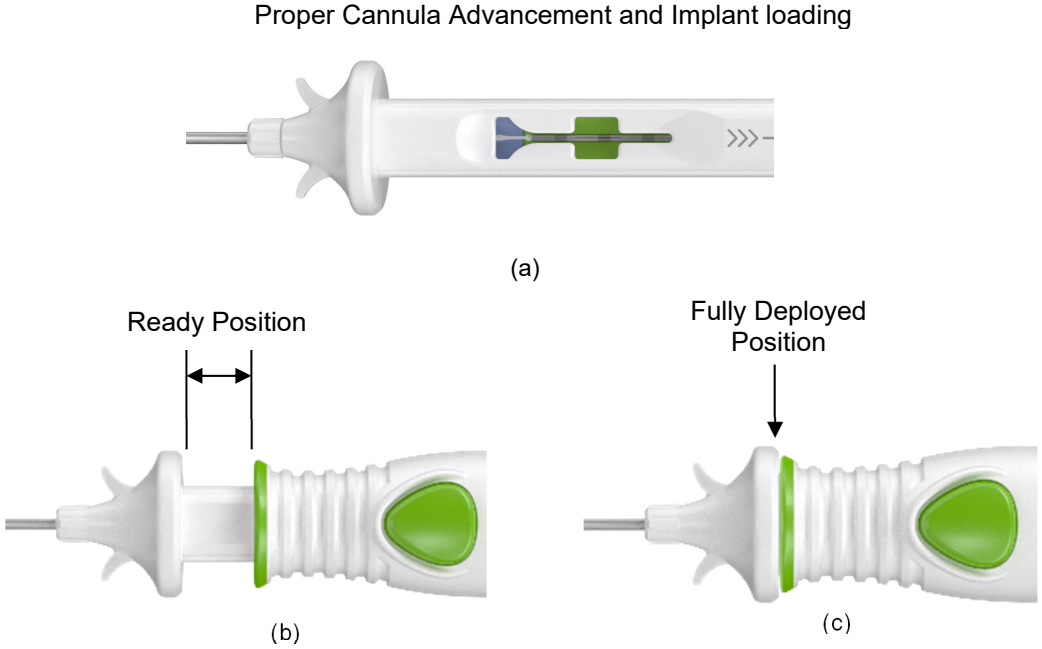
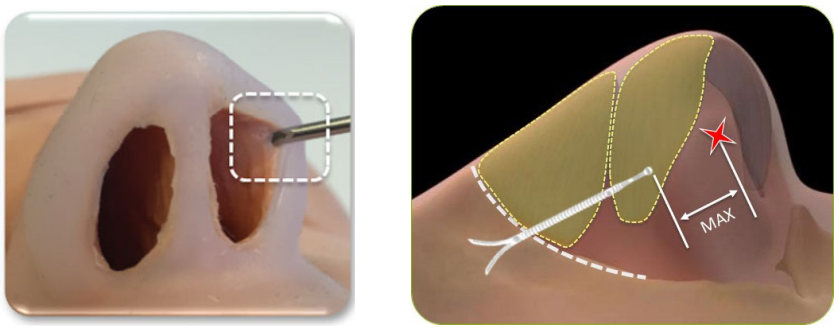


Figure 6: Images showing (a) Proper cannula advancement and *Implant* loading, (b) *Delivery Device* Ready Position, (c) *Delivery Device* Deployed Position

Implant Delivery:

8. Identify the cannula insertion point, **Figure 7(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 7(b)** below.



(a) (b)

Figure 7: 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

9. The ala may be everted using a double prong skin hook under direct visualization. Ensure the cannula bevel and reference mark is facing medial before pierce. Insert the *Delivery Device* cannula perpendicular to the septum through the nasal vestibular lining of the lateral wall until the tip reaches the caudal aspect of the lower lateral cartilage. The cannula reference mark may be used as an aid to determine insertion depth. Approximate *Delivery Device* orientation, cannula trajectory and depth are shown in **Figure 8** below.

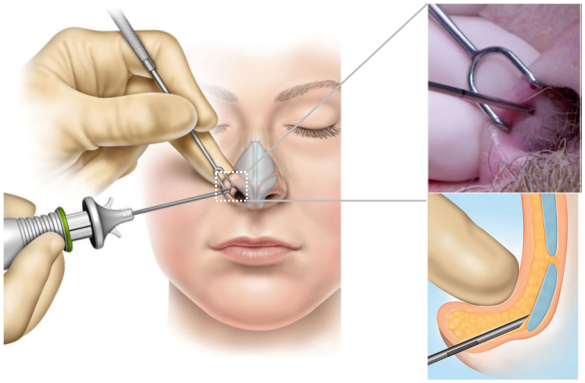


Figure 8: Images showing the approximate *Delivery Device* orientation, cannula trajectory and pierce point.

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

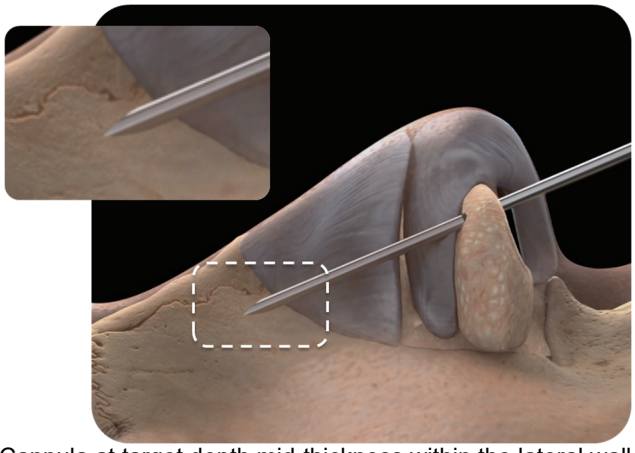


Figure 9: Cannula at target depth mid-thickness within the lateral wall structure.
The intended position of the cannula tip and cannula are shown in the magnified views

13. Use 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. The *Delivery Device* fork orientation features should be parallel to the Maxilla bone during implant deployment.

14. When the cannula is in the appropriate location and orientation, press and release the deploy button and carefully advance the outer handle to the deployed position. Keep fingers proximal to the green ring when deploying the *Implant*. Stabilize the cannula with non-dominant hand during deployment. 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.

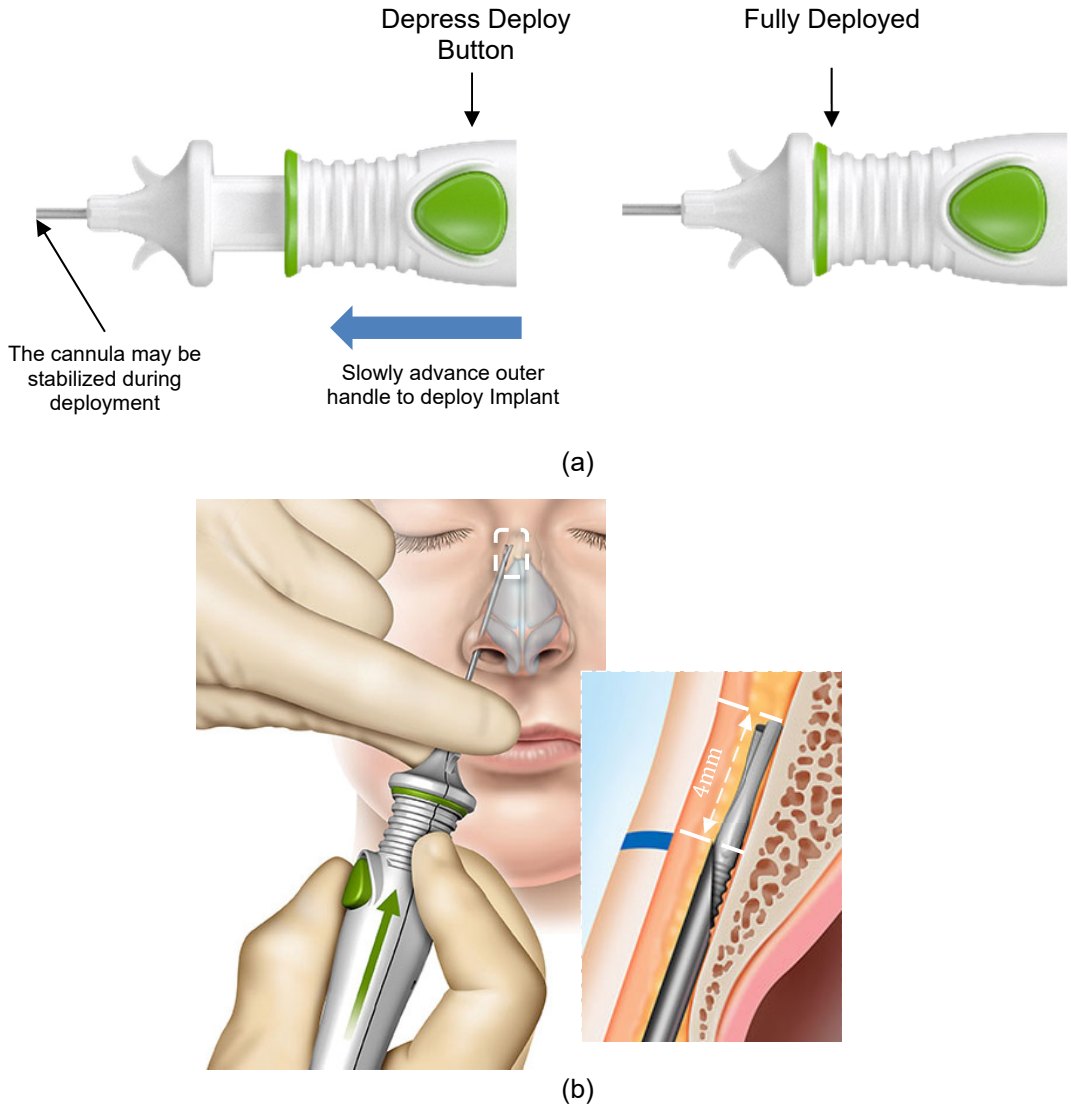


Figure 10: Images of the *Delivery Device* proximal end and cannula positioned within the lateral wall showing Implant deployment process including: (a) Actuation of the *Delivery Device* outer handle and (b) *Implant* forks expanded approximately 4 mm distal to the cannula tip after deployment.

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. Apply all distal pressure to the outer handle to ensure minimal *Delivery Device* movement during deployment.

15. Following deployment, apply slight compression over deployed forks cephalic to the cannula tip (**Figure 11a)** and 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.

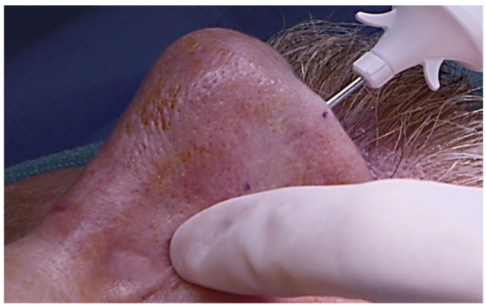


Figure 11(a)

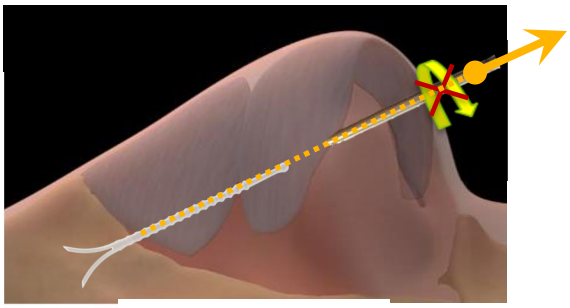


Figure 11(b)

Figure 11: Images of the *Delivery Device* withdrawal: (a) compression over deployed forks cephalic to the cannula tip (b) withdrawal without

16. After complete withdrawal of the cannula, 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.
17. If multiple implantation attempts are required, each insertion should utilize a different pierce point within the mucosa and follow a different cannula trajectory.
18. Repeat steps 1-17 for each implanted device.
19. Counsel the patient to avoid post-procedure 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 Delivery Device should be disposed of in a biohazard sharps disposal container. The *Implant Positioning Guide* and *Implant* container may be disposed of along with standard medical waste.

GRAPHIC SYMBOLS CONTAINED IN DEVICE LABELING

STERILE R Sterilized using irradiation	 Use by date	 Do not re-use	 Upper limit of temperature
LOT Batch code	 Keep dry	Rx only Caution: Federal law restricts this device to sale by or on the order of a Physician	 Do not use if package is damaged
REF Catalogue number	 Non-pyrogenic	 Date of manufacture	 Quantity in package/box
 Manufacturer	 Keep away from sunlight	 Consult instructions for use	

TRADEMARKS AND PATENTS

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Consult a list of patents covering this product at https://ent.stryker.com/patents.

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