

# PROPEL<sup>®</sup> Mini Straight Delivery System

## Instructions for Use

**CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. THESE INSTRUCTIONS FOR USE MUST BE USED IN CONJUNCTION WITH THE PROPEL MINI (mometasone furoate 370 ug) SINUS IMPLANT INSTRUCTIONS FOR USE.**

**STERILE:** Sterilized by irradiation. Do not use if the package is open or damaged.  
**STORAGE:** The product should be stored at room temperature (approximately 25° C) with excursions permitted to 15-30° C.  
**SINGLE USE:** Product is supplied sterile and for single use only. Do not reprocess or reuse.

**Caution:** Federal law (USA) restricts this product to sale by or on the order of a physician.

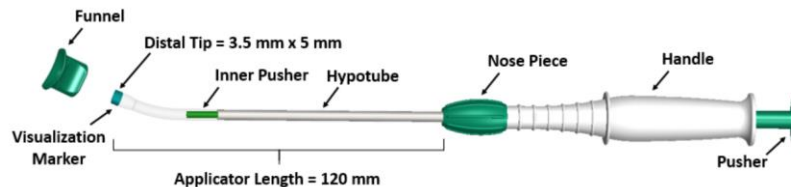
### PRODUCT DESCRIPTION

The PROPEL Mini Straight Delivery System is designed for loading and delivery of the PROPEL Mini (mometasone furoate 370 ug) Sinus Implant.

For PROPEL Mini (mometasone furoate 370 ug) Sinus Implant description, see full PROPEL Mini Instructions for Use.

### Component Description

The PROPEL Mini Straight Delivery System has a straight shaft with a slight angulation (11°) at the tip. The delivery system is provided as an alternative option to access the ethmoid sinus and insert the PROPEL Mini (mometasone furoate 370 ug) Sinus Implant. A funnel is provided to assist in the loading of the implant into the delivery system.



**Other Components Required:** The PROPEL Mini (mometasone furoate 370 ug) Sinus Implant is sold separately and packaged with a crimper, loading tool, funnel and primary (curved) delivery system.

### INDICATIONS AND INTENDED USE

**Straight Delivery System:**

The PROPEL Mini Straight Delivery System is designed for delivery of the PROPEL Mini Sinus Implant to the ethmoid sinus. The PROPEL Mini Straight Delivery System is intended to be used by a physician under endoscopic visualization. The PROPEL Mini Straight Delivery System is intended for single patient use only. The PROPEL Mini Straight Delivery System is intended for bilateral use within a single patient.

**Implant:**

The PROPEL Mini Sinus Implant is intended for use in patients  $\geq 18$  years of age following ethmoid/frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening. The PROPEL Mini Sinus Implant separates/dilates surrounding mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces inflammation. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.

### CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS

For contraindications, warnings, and precautions, see full PROPEL Mini Sinus Implant Instructions for Use.

### DRUG INFORMATION, DRUG INTERACTIONS, CARCINOGENICITY, GENOTOXICITY AND REPRODUCTIVE TOXICITY, PREGNANCY, LACTATION, DOSAGE AND ADMINISTRATION

For PROPEL Mini Sinus Implant information, including drug information, drug interactions, carcinogenicity, genotoxicity & reproductive toxicity, pregnancy, lactation, and dosage & administration, see full PROPEL Mini Sinus Implant Instructions for Use.

### DIRECTIONS FOR USE

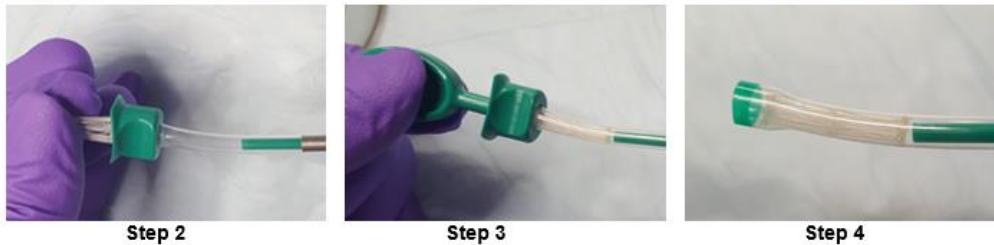
1. Remove the implant from its packaging along with the crimper and loading tool. Remove the PROPEL Mini Straight Delivery System and associated funnel from its packaging. Crimp implant per the PROPEL Mini Sinus Implant Instructions for Use. Note: Ensure the funnel is attached to the distal end of the delivery system.
2. Insert the compressed implant into the funnel attached to the distal tip of the PROPEL Mini Straight Delivery System.
  - a. Note: The implant may be compressed and loaded into the delivery system tip up to two times. Refer to PROPEL Mini Sinus Implant Instructions for Use for full crimping and reloading instructions.
  - b. Note: The PROPEL Mini Straight Delivery System may be used to deploy an implant up to four times.
3. Use the loading tool to push the implant past the opening of the funnel.

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- Carefully remove the funnel, taking care not to dislodge the implant from the tip of the delivery system. If the implant begins to withdraw from the tip during funnel removal, replace the funnel and use the loading tool to push the implant back into the delivery system, then gently squeeze the tip of the delivery system to hold the implant in place while removing the funnel.









**CAUTION:** Do not leave the PROPEL Mini Sinus Implant in the crimped state for more than three minutes prior to placement.



- For adequate visualization, ensure hemostasis in operated sinus cavities prior to insertion. Advance the delivery system into the ethmoid sinus cavity using endoscopic visualization.
- Ensure that the delivery system is oriented so the distal tip is angled superiorly toward the posterior roof of the ethmoid sinus cavity.
- Align the distal tip of the inner pusher with the anterior edge of the middle turbinate.
- Insert the implant by depressing the pusher while simultaneously withdrawing the delivery system.
- Confirm final placement by endoscopic visualization. Confirm the proximal loops of the implant align with the anterior edge of the middle turbinate. Confirm the implant is well apposed to the tissue to maximize drug delivery. To adjust the position of the implant, use standard surgical instruments.

### CLINICAL TRIALS

For Clinical Trial and Adverse Events, see full PROPEL Mini Sinus Implant Instructions for Use.

Symbols Used on Product Labeling			
<b>REF:</b> Reference Number	 Use By	 Single Use]	 15°C  30°C Room Temperature
 Lot Number	 Read Instructions Prior to Use	 Sterilized using Irradiation	 Manufacturer

### Product Information Disclosure

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