The inactive ingredients on the sinus implant are poly-(DL-lactide-co-glycolide) and polyethylene glycol. Poly-(DL-lactide-co-glycolide) is an amorphous biodegradable polymer. The chemical structure is shown below.

Polyethylene glycol is a hydrophilic polyether compound that is highly flexible. It is non-toxic and non-immunogenic. The chemical structure is shown below.

Implant Component Description

The PROPEL® sinus implant is composed of a synthetic biodegradable co-polymer, poly(L-lactide-co-glycolide) (PLG). The implant is biodegradable and is designed to approximate the size and variability of the post-surgical ethmoid sinus anatomy. Once inserted, the implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and deliver drug to the mucosa. The PROPEL® implant should be inserted by a physician using endoscopic visualization. A delivery system is provided to access the ethmoid sinus and insert the implant.

Drug Component Description

The implant separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema. It is not known if mometasone furoate is excreted in human milk. Because other corticosteroids are excreted in human milk, the PROPEL implant should be used only if the potential benefits justify the potential risk.

No long-term studies in animals have been performed to evaluate the carcinogenic potential of the implant.

CARCINOGENICITY, GENOTOXICITY AND REPRODUCTIVE TOXICITY

No drug-drug interaction studies have been conducted with the implant.

CARCINOGENICITY, GENOTOXICITY AND REPRODUCTIVE TOXICITY

No teratogenic studies in animals have been performed to evaluate the teratogenic potential of the implant.

PREGNANCY

There have been no controlled studies in pregnant women using the PROPEL sinus implant. The PROPEL sinus implant should not be used during pregnancy only if the potential benefits justify the potential risk.

LACTATION

It is not known if mometasone furoate is excreted in human milk. Because other corticosteroids are excreted in human milk, the PROPEL implant should be used only if the potential benefits justify the potential risk.

DOSAGE AND ADMINISTRATION

Each PROPEL implant contains 370 µg of mometasone furoate which is gradually released over time.

DIRECTIONS FOR USE

1. Open the implant and delivery system from its protective packaging using sterile technique. Inspect for any obvious damage. NOTE: Ensure the funnel is attached to the distal end of the delivery system.
2. The implant must be compressed and loaded into the tip of the delivery system prior to use:
   a. Gently slide implant off its holder.
   b. Grasp the implant between the fingers of both hands and gently compress the implant.
   c. Insert compressed implant into the funnel attached to the distal tip of the delivery system.
   d. Press firmly to compress the implant into the delivery system. CAUTION: Do not force the implant into the delivery system.
   e. Carefully remove the funnel, being careful 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 gently squeeze the tip of the delivery system to hold implant in place.
3. For adequate visualization, ensure hemostasis in operated sinus cavities prior to insertion. Advance the Delivery System into the sinus cavity using endoscopic visualization. To insert the implant:
   a. Ensure the Delivery System is oriented so the distal tip is curved superiorly toward the posterior roof of the sinus cavity.
   b. Align the proximal end of the implant with the anterior edge of the middle turbinate.
   c. Insert the implant by depressing the plunger while simultaneously withdrawing the delivery system.
4. Confirm final placement by endoscopic visualization. Confirm the proximal loops of the implant align with the anterior edge of the middle turbinate (see illustration below). Confirm the implant is well apposed to the tissue to maximize drug delivery. To adjust the position of the implant, use standard surgical instruments.

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The efficacy and safety of the PROPEL® implant, when used in adult patients with chronic sinusitis undergoing frontal ethmoid sinus surgery (FESS), have been studied in three prospective clinical trials conducted in the United States and involving 205 patients. The principal safety and efficacy information is derived from the ADVANCE II clinical trial and is supported by the ADVANCE clinical trial and CONSENSUS II pilot trial. In the three studies, implant placement occurred following ethmoidectomy. Implants were successfully placed in a total of 600 sinuses in 205 patients. Of the 600 implants, 16 (4%) were removed and replaced immediately after deployment due to suboptimal apposition, 0.8% were damaged during preparation, in these 3 cases, the implant was removed and a new one placed.

The ADVANCE II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 105 patients at 11 study centers. The study utilized an inpatient control design to assess the safety and efficacy of the PROPEL® sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the need for post-operative intervention at day 30, determined from video-endoscopies reviewed by a panel of independent blinded sinus surgeons. Post-operative intervention was a composite endpoint that included surgical intervention required to separate an adhesion and/or to perform conjunctive intervention to remove recurrent sinusitis or sinonasal inflammation, adenoids and/or poly turbinates. Additional efficacy endpoints were determined by endoscopic grading of the nasal cavity at day 30. The primary safety endpoint was ocular safety defined as absence of clinically significant sustained elevation (≥10 mm Hg) in intraocular pressure through Day 60. Ocular examinations also included assessment of changes in or development of lens opacities.

The PROPEL® implant delivery success rate was 100%. The primary efficacy endpoint was met demonstrating a statistically significant reduction in the need for post-operative interventions at day 30 (p=0.028). There were no clinically significant increases in intraocular pressure and no clinically significant changes from baseline in lens opacities.

### POTENTIAL ADVERSE EVENTS

- **Swallowing implant or implant fragments**
- **Pain/pressure/headache may result from the adherence of crusting to, or presence**
- **glaucoma/elevation in intraocular pressure**
- **vomiting**
- **epistaxis**
- **hypersensitivity reactions**

**Adverse Events from All Three Clinical Trials**

<table>
<thead>
<tr>
<th>Adverse Event Type</th>
<th>Occurred in ≥2% of Patients Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical</strong></td>
<td>105</td>
</tr>
<tr>
<td><strong>Non-surgical</strong></td>
<td>105</td>
</tr>
</tbody>
</table>

**Adverse Events Listed in Tabular Form for the ADVANCE II and ADVANCE III trials and through Day 30 at the ADVANCE II trial.**

### POTENTIAL ADVERSE EVENTS

Risks associated with the use of the PROPEL® sinus implant are anticipated to be similar to those experienced by patients who undergo placement of sinus implants or packing. This is a list of potential adverse events associated with the PROPEL® implant:

- **Swallowing implant or implant fragments**
- **Foreign body response, including formation of granulation tissue**

### SECONDARY EFFICACY RESULTS

#### Primary endpoints:

- Nasal tissue score (NRS) 22

#### Secondary endpoints:

- Total Rhinologic Symptom Disease Instrument (RSDI)
- Sino-Nasal Outcome Test (SNOT-22)
- Middle Turbinate Lateralization

### CLINICAL TRIALS

**CONSENSUS II pilot study:** A randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients at 5 study centers. A total of 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version. The study utilized an inpatient control design to assess the safety and efficacy of the PROPEL® sinus implant compared to the non-drug control version of the implant. Thirty-eight patients were enrolled in this group and received the 23 mm implants. The other group consisted of 12 patients who underwent the same procedure and were treated with placebo implants of the same length. The study utilized a prospective design and compared the findings with baseline data collected before the procedure. All patients were treated with corticosteroids and antibiotics for a period of 1 week before and after the procedure.

**ADVANCE II**

- **Premature displacement of implant or implant fragments**
- **Swallowing implant or implant fragments**
- **Headache, pressure or pain from the adherence of crusting to, or presence**
- **Middle turbinate lateralization**
- **Significant Adhesions**
- **Coated Struts**
- **Implant delivery success rate**

### CLINICAL TRIALS

**POTENTIAL ADVERSE EVENTS**

#### Adverse Event Type

- **Swallowing implant or implant fragments**
- **Pain/pressure/*headache* may result from the adherence of crusting to, or presence**
- **glaucoma/elevation in intraocular pressure**
- **vomiting**
- **epistaxis**
- **hypersensitivity reactions**

### Adverse Events

Adverse events that may be related to the implant are reported in ≥2% of patients across all three trials are displayed in the table below.

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**Adverse events related to implant are reported in ≥2% of patients across all three trials are displayed in the table below.**

### Product Information Disclosure

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