The PROPEL Mini sinus implant underwent pharmacokinetic testing. Following bilateral drug-eluting PROPEL treatment and delivery to the middle turbinate, the PROPEL Mini implant was inserted in a patient under endoscopic visualization. A delivery system is provided to achieve the ethmoid or frontal sinus and insert the implant. A crimper, loading tool, and funnel are provided to assist in the crimping and loading of the implant into the delivery system.

The implant must be compressed and loaded into the tip of the delivery system prior to use. No drug-drug interaction studies have been conducted with the implant.

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

INDICATIONS AND INTENDED USE
The PROPEL Mini sinus implant is intended for use in patients ≥ 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, which provides for gradual release of the drug. Routine debridement may be performed as part of the usual post-operative care.

The PROPEL Mini implant is designed for single patient use only. Do not reprocess or reuse.

The implant is not designed to be modified by the physician. The implant must be placed under endoscopic visualization. The implant is not designed to be removed by the physician. The implant is not intended to be compressed and loaded into the delivery system more than two times. The implant must be placed under endoscopic visualization. The implant exhibits no antireflective properties. The implant is not designed to be removed by the physician. The implant is not designed to be modified by the physician. The implant is not designed to be removed by the physician. The implant is not designed to be removed by the physician.

The implant is biocompatible and is designed to accommodate the size and variability of the post-surgical ethmoid or frontal sinus anatomy. Once inserted, the implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain patency of the post-surgical ethmoid or frontal sinus opening. The implant reduces the need for post-operative interventions such as surgical adhesion lysis and/or use of oral steroids.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO 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.

CONTRAINDICATIONS:
Do not use if the package is open or damaged.

The implant is not designed to be modified by the physician. The implant is not designed to be removed by the physician. The implant is not intended to be compressed and loaded into the delivery system more than two times. The implant must be placed under endoscopic visualization. The implant exhibits no antireflective properties. If foreign body reaction may occur in persons with most surgical adjuncts. The implant is not designed to be removed by the physician. The implant is not designed to be modified by the physician. The implant is not designed to be removed by the physician.

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CLINICAL TRIALS

PROPEL Mini is a smaller version of the PROPEL sinus implant. The efficacy and safety of the PROPEL implant, when used in adult patients with chronic sinusitis undergoing functional endoscopic sinus surgery (FESS), have been studied in three prospective clinical trials conducted in the United States and totaling 1207 patients. The principal safety and efficacy information is derived from the ADVANCE II clinical trial and CONSIGNMENT II pilot study. In all three studies, implant placement occurred following endoscopically. Implants were successfully placed in a total of 405 sinuses in the 205 patients. Of the 405 implants, 16 (4%) were removed and replaced immediately after deployment due to sub-optimal apposition, crossing or inadvertent removal in the vestibule region. In these 3 cases, a new implant was used successfully.

The ADVANCE II study was a prospective randomized, double-blind, concurrently controlled trial that enrolled 105 patients in 11 study centers. The study utilized an intranasal control design to assess the safety and efficacy of the PROPEL sinus implant compared to the control implant. The primary safety endpoint was oral steroid intervention required to resolve recurrent ethmoid sinus inflammation, edema and/or polyp recurrence. Additional efficacy endpoints were determined by endoscopic grading by clinical investigators at the study centers. The primary safety endpoint was not met and no statistically significant differences were observed. The secondary efficacy endpoints were determined by endoscopic measures taken by investigators at specified time points.

The CONSIGNMENT II pilot study was a randomized, double-blind, concurrently controlled trial that enrolled 60 patients at 3 study centers. A total of 46 patients received the 23 mm PROPEL sinus implant and 14 patients received a placebo implant. The study utilized an intranasal control design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting control version of the implant. Thirty-eight patients were enrolled in the group and received the 23 mm implants. The other group of 12 patients were enrolled in the group and received the 18 mm implants. The study ended early due to the need for pre-operative intervention at Day 30, as determined by an independent clinical investigational committee based on end-point data. Post-operative intervention was assessed for the 23 mm implants only, and was conducted following endoscopic grading at Baseline, Day 7, Day 21, and Day 90.

The PROGRESS study was a prospective, randomized, blinded, controlled trial that enrolled 80 patients in 11 study centers. The study utilized an intranasal control design to assess the safety and efficacy of the PROPEL Mini sinus implant when placed following on surgery or sinus side compared to surgery alone on the contralateral side. In these 2 cases, a new implant was used successfully.

OBSERVED ADVERSE EVENTS

Adverse events were recorded throughout the 90-day follow-up period. Adverse events were collected using standard case report forms. Adverse events were confirmed by independent review of the video recordings. The incidence rate of product-related adverse events on a by-patient count was 6.2%. There were no clinically significant changes from baseline in sinus volumes or IOP. The mean changes from baseline to Day 60 and 6 months in total RSGD score were -0.2 and -0.17, respectively (p=0.991). For the 23 mm, the changes were -1.7 and -1.7, respectively (p=0.991). All changes from baseline in RSGD, BDRT, and TBOG were statistically significant (p<0.001).

In the PROGRESS study (mini cohort) with 80 patients, there were no implant-related serious adverse events or adverse events resulting in discontinuation of the study. The overall incidence rate of product-related adverse events was 1.5%: three patients had adverse events of headache, left upper eyelid swelling, and epistaxis. All three events resolved without sequelae.

The risks potentially associated with use of the PROPEL implant are:

- Aspiration of small implant fragments (not observed in clinical trials)
- Foreign body response, including formation of granulation tissue
- Pain/pressure/headache may result from the adherence of crustings to, or presence of the implant
- Swelling of implant or implant fragments
- Peri-implant edema or inflammation: may result from the adherence of crustings to, or presence of the implant
- Aspiration of small implant fragments (not observed in clinical trials)
- Foreign body response, including formation of granulation tissue

There may be other potential adverse effects that occur which are currently unforeseen.

Symbols Used on Product Labeling

<table>
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<tr>
<th>REF.</th>
<th>Number</th>
<th>Use By</th>
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<td></td>
<td></td>
<td></td>
<td>Sterilized by</td>
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</tr>
</tbody>
</table>

POTENTIAL ADVERSE EVENTS

Rates associated with the use of the PROPEL sinus implants are anticipated to be similar to those experienced by patients undergoing placement of sinus implant or packing.

- Swelling of implant or implant fragments
- Peri-implant edema or inflammation: may result from the adherence of crustings to, or presence of the implant
- Aspiration of small implant fragments (not observed in clinical trials)
- Foreign body response, including formation of granulation tissue

Potential risks or side effects associated with intranasal mometasone furoate include:

- Nasal irritation
- Hypersensitivity reactions
- Localized infection (bacterial, fungal or viral) in the nose or paranasal sinuses
- Nasal dryness
- Sensitivity to secondary infections due to bacteria, viral or viruses
- Exposure to intranasal pressure

Potential risks or general adverse effects associated with mometasone furoate:

- Attention of the HPA axis including growth suppression
- Immunosuppression
- Arthritis
- Cardiovascular reactions
- Hepatitis
- Cushing's
- Glaucoma, increased intraocular pressure

For mometasone furoate, a potential risk is that surgical intervention may be required to address some of these adverse events.

In the PROGRESS study (mini cohort) with 80 patients, there were no implant-related serious adverse events or adverse events, resulting in a 0% incidence rate of implant-related adverse events. Five adverse events (headache, left upper eyelid swelling, recurrent sinusitis, increased intraocular pressure) were judged by clinical investigators as having an uncertain relationship to the implant. All 5 events resolved without sequelae. No patients withdrew due to an adverse event and no death occurred in any of the three trials. Adverse events (regardless of relationship to implant) reported in 42% of patients across all three trials are displayed in the table below.

<table>
<thead>
<tr>
<th>Potential Adverse Events</th>
<th>Incidence Rate (%)</th>
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<tr>
<td>Headache</td>
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<tr>
<td>Left upper eyelid swelling</td>
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<tr>
<td>Epistaxis</td>
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<tr>
<td>Localized infection</td>
<td>1.3</td>
</tr>
<tr>
<td>Intranasal pressure</td>
<td>1.3</td>
</tr>
</tbody>
</table>

Product Information Disclosure

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