Instructions For Use

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.

INDICATIONS AND INTENDED USE

The PROPEL Mini implant is comprised of a synthetic bioabsorbable co-polymer, poly(L-lactide-co-glycolide), PLG.

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

DRUG INTERACTIONS

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

The use of the PROPEL Mini Sinus Implant is contraindicated in the following patients:

• Patients with suspected or confirmed hypersensitivity and/or intolerance to mometasone furoate.
• The implant is not designed to be modified 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 anticoagulant properties.
• Exogenous body reaction may occur as possible with most surgical adjuncts.
• In rare instances, the physicochemical condition associated with sinus surgery, both with and without sinus implants or packing, may present a risk of toxic shock syndrome (TSS).
• Inflammatory and fibrotic reactions. The safety and effectiveness of the implant in pediatric patients have not been established.

Other Components Available: The PROPEL Mini Straight Delivery System (5-pack) is sold and packaged separately as an alternative option for ethmoid sinus access and implant delivery. The 5-pack includes:

• Straight Delivery System S 4
• Funnels S 5

INDICATIONS AND INTENDED USE

The PROPEL Mini Sinus Implant is intended for use in patients ≥ 15 years of age following ethmoid sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening. The PROPEL Mini Sinus Implant is intended to be delivered through a variety of natural and artificial pasages in the sinus cavity.

PRODUCT DESCRIPTION

The PROPEL Mini Sinus Implant consists of a synthetic bioabsorbable co-polymer, poly(lactide-co-glycolide), PLG.

The implant is bioabsorbable 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 sinus patency and delivery of drug to the mucosa. The PROPEL Mini implant should be inserted by a physician under endoscopic visualization. A delivery system is provided to access the ethmoid or frontal sinus and insert the implant. A compact, loading bar, and funnel are provided to assist in the crimping and loading of the implant into the delivery system.

The implant is not intended to be compressed and loaded into the delivery system more than two times. The implant is not designed to be modified by the physician.

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The implant must be placed under endoscopic visualization.

The implant exhibits no anticoagulant properties.

Exogenous body reaction may occur as possible with most surgical adjuncts.

In rare instances, the physicochemical condition associated with sinus surgery, both with and without sinus implants or packing, may present a risk of toxic shock syndrome (TSS).

Pharmacokinetics: The PROPEL Sinus Implant undergoes pharmacokinetic testing. Following bilateral drug-engaging PROPEL implant placement after sinus surgery for chronic sinusitis and subsequent weekly monthly intranasal wiping for 4 weeks in 5 adult patients, plasma mometasone furoate concentrations were not quantifiable at any time point. Mean cortisol concentrations were within normal limits.

DRUG INTERACTIONS

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

CARCINOGENICITY, GENOTOXICITY AND REPRODUCTIVE TOXICITY

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

PREGNANCY

There have been no controlled studies in pregnant women using the PROPEL Mini Sinus Implant. The PROPEL Mini Sinus Implant should 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 Mini implant should be used only if the potential benefits justify the potential risk.

DOSEAGE AND ADMINISTRATION

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

DIRECTIONS FOR USE

1. After the implant and delivery system from their protective packaging using sterile technique. Insert 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.

3. The implant is not designed to be modified by the physician.

4. The implant is not intended to be compressed and loaded into the delivery system more than two times.

5. 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.

6. The implant is not intended to be modified by the physician.

7. Confirm final placement by endoscopic visualization. Confirm the loops of the implant support the frontal sinus opening. Confirm the implant is well apposed to the tissue to maximize drug delivery. To adjust the position of the implant, use standard surgical instruments.

Post-implant care:

• As part of routine post-operative care, frequent use of saline sprays, rinses or irrigations is recommended to keep the implant moist.
• Routine debridement may be performed as part of the usual post-operative care.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

STERILE:

Stereilized by irradiation. Do not use if the package is open or damaged.

SINGLE USE:

The product should be stored at room temperature (approximately 25º C) with excursions permitted to 15-30º C.

Customer Service: 1-866-531-6004

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IFU 00341 Rev R
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**Primary Efficacy Results**

<table>
<thead>
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<th>Condition</th>
<th>Treatment</th>
<th>Control</th>
<th>p-value</th>
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<tbody>
<tr>
<td>Nasal Obstruction</td>
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<td>SNIV</td>
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<tr>
<td>Septum deviation</td>
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<tr>
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<td>Operative intervention</td>
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**Secondary Efficacy Results**

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<td>Frequency and severity of adhesion/scarring</td>
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<td>Polypoid edema and inflammation</td>
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**Potential Adverse Events**

- Headache
- Myalgia
- Fatigue
- Influenza-like illness
- Rhinorrhea
- Sore throat
- Nasal congestion
- Nasopharyngitis
- Sinusitis
- Frank polyps
- Septal deviation
- Nasal polyps
- Need for surgical intervention
- Orbital mass
- Upper airway obstruction
- Ocular examination
- Operative intervention

**Product Information Disclosure**

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