PROPEL® Contour
(mometasone furoate implant, 370 μg)
Instructions For Use

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

STERILE
Standardized to sterilization. Do not use if the package is open or damaged.

STORAGE
The product should be stored at room temperature 20-25°C with excursions permitted to 15-30°C.

SINGLE USE
Product is supplied sterile and for single use only.

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

PRODUCT DESCRIPTION
The PROPEL® Contour sinus implant provides sustained release of mometasone furoate via a bioabsorbable sinus implant. A delivery system is provided to insert the implant.

Drug Component Description
The PROPEL Contour sinus implant contains mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. Mometasone furoate (MF) is a white to off-white powder. The chemical name is 9α,21-dihydroxy-11α,17β-dihydroxy-16α-carboxyprogesterone 20α,21-dichloro-11α,17β,20α,21-tetrahydroxyprogesterone 20β-hydroxy-3,20α,21-trihydroxy-17β-estradiol, and its molecular weight is 542.45 g/mol. The chemical structure of a hydrophobic drug is practically insoluble in water. Mometasone furoate is stable under aqueous, acidic and oxidative conditions. Mometasone furoate can degrade under systemic basic, thermal and photolytic conditions. The chemical structure is shown below. The drug is embedded in a bioabsorbable polymeric matrix containing poly(L-lactide-co-glycolide) and polyethylene glycol (PEG) reactive ingredients which provide for gradual release of the drug.

DRUG INFORMATION
Indications and Intended Use
The PROPEL Contour sinus implant is intended for use in patients aged 18 years or older to maintain patency of the frontal and maxillary sinus ostia following endoscopic sinus surgery. The implant is designed to maintain sinus patency and deliver drug to the mucosa. The implant should be inserted by a physician with endoscopic visualization. A delivery system is provided to access the frontal and maxillary sinus ostia and deploy the implant. A loading tool and funnel are optional accessories provided to assist in loading the implant into the delivery system.

Contraindications:
- Patients with suspected or confirmed hypersensitivity and/or intolerance to mometasone furoate.
- Contraindicated in patients with a history of TSS or known sensitivity to the Chemical structures shown below.

Warnings:
- The PROPEL Contour sinus implant is designed for single patient use only. Do not reuse or repurpose.
- Do not use if the package is open or damaged.

Implant Component Description
The PROPEL Contour sinus implant is comprised of a bioabsorbable co-polymer, poly(L-lactide-co-glycolide), P(LG). The implant is bioabsorbable and is designed to accommodate the size and variability of the surgically enlarged frontal and maxillary sinus ostia. Once inserted, the implant is designed to be well-maintaining against the mucosa of the surgically enlarged sinus ostium in order to maintain sinus patency and deliver drug to the mucosa. The implant should be inserted by a physician with endoscopic visualization. A delivery system is provided to access the frontal and maxillary sinus ostia and deploy the implant. A loading tool and funnel are optional accessories provided to assist in loading the implant into the delivery system.

Mechanism of Action
The PROPEL Sinus implant underwent pharmacokinetic testing. Following bilateral drug-eluting PROPEL implant placement after sinus surgery for chronic sinusitis and subsequent weekly morning blood sampling for 4 weeks in 5 adult patients, plasma mometasone furoate concentrations were quantifiable at any time point. Mean cortisol concentrations were within normal limits.

Indications and Intended Use
Each PROPEL Contour sinus implant contains 370 μg of mometasone furoate which is gradually released over time.

DIRECTIONS FOR USE

1. Remove the implant and delivery system from its protective packaging using sterile technique. Inspect for any obvious damage.
2. Using your fingers, gently bend the tip of the applicator to the desired angle while supporting the tubing with your fingers. The useable range of the delivery system is from 70 to 110 degrees.
3. a. Insert the compressed implant into either the attached funnel (if applicable) or directly into the distal tip of the delivery system.
   b. Carefully remove the tip of the implant holder, being careful not to grasp or dislodge the implant.
   c. Gently lift the implant off of the base of the applicator holder.
   d. Grasp the implant between the fingers of both hands and gently compress the implant.
   e. Insert compressed implant into either the attached funnel (if applicable) or directly into the distal tip of the delivery system.
   f. If the funnel is attached, use the loading tool to push the implant past the opening of the funnel. If the funnel is not attached, continue to push the compressed implant directly into the delivery system until it is flush with the distal tip.
   g. If the funnel is attached, carefully remove the funnel, taking care not to detach 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 maintain patency of the sinus ostium.
   h. The implant must be compressed and loaded into the delivery system tip-up to tip-down twice.

CAUTION: Do not leave the implant in the compressed state for more than three minutes prior to placement.

Step 1a
Step 1b
Step 2a
Step 2b
Step 3a
Step 3b
Step 4a
Step 4b
Step 5a
Step 5b

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An independent blinded reviewer (see table below). Holm’s step-down procedure used to control for family-wise type I error. Secondary efficacy endpoints showed statistically significant reductions in the need for postoperative interventions ($p=0.0039$), which were compared to the control sides, representing a relative reduction of 42.9%.

The PROGRESS study was a prospective, randomized, blinded, controlled study that enrolled 80 patients across 12 study centers. The EXCEED study was a prospective, single-arm, open-label, feasibility trial designed to assess the performance, safety, and feasibility of the PROPEL Contour sinus implant placement in the frontal and maxillary sinuses in patients with chronic sinusitis following ESS in the office and operating room settings. Fifteen of 16 patients enrolled at 2 study sites were eligible to participate. The EXCEED study showed an overall implant delivery success rate of 97.5% (100% in frontal sinuses; 96.2% in maxillary sinuses), demonstrating that the primary efficacy endpoint was met. No serious adverse events were reported. In the EXCEED study, no other adverse events were attributed to the PROPEL Contour sinus implant. Observed improvements in Day 80 included a 46% increase in ostial patency, a 75% reduction in polyoid edema in the frontal recess/FSO, and a 38.1 mm decrease in inflammation score. The mean MOTE-2 score at Day 80 showed a treatment effect size of 1.16, representing a large clinical benefit.

The PROGRESS study demonstrated that PROPEL Contour sinus implant placement in the FSO was successful (100% implant delivery), safe, and effective in significantly reducing the need for postoperative interventions in the FSO at Day 30 ($p=0.0023$), as judged by an independent sinus surgeon with video-endoscopy. The primary efficacy endpoint was the success rate for postoperative interventions of Day 30, as determined by independent, blinded, sinus surgeons based on video-endoscopy review. Post-operative intervention was a complete explant that included surgical intervention to remove obstructive exudates or scarring and remove any debris evident on the surgical wound site. Sinus surgeons were blinded to the patients’ treatment group.

**ADVERSE EVENTS**

**OBSERVED ADVERSE EVENTS**

PROPEL Contour sinus implant is a drug-releasing sinus implant that is transferable in size than the PROPEL Mini, to accommodate the size and variability of the enlarged sinus cavity. Two prospective clinical trials (EXCEED and PROGRESS) conducted in the United States involved 150 and 120 PROPEL Contour sinus implants. In the EXCEED study, 12 serious adverse events were reported, resulting in a 4% incidence rate of implant-related adverse events. No patients withdrew due to an adverse event, and no deaths occurred. In the PROGRESS study, 8 patients, no serious adverse events or adverse events were observed, resulting in a 0% incidence rate of implant-related adverse events. All adverse events (headache, epistaxis, allergic reactions) were judged by clinical investigators as being unrelated to the implant. No patients withdrew due to an adverse event and no deaths occurred. Adverse events (regardless of relationship to implant) were reported in 1% of patients in the PROGRESS study are summarized in the table below.

<table>
<thead>
<tr>
<th>Adverse Events (n=80)</th>
<th>PROGRESS Study Occurrence</th>
<th>Relative Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>7</td>
<td>11.5%</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>6</td>
<td>10.0%</td>
</tr>
<tr>
<td>Allergic reactions</td>
<td>2</td>
<td>3.3%</td>
</tr>
<tr>
<td>Nasal irritation</td>
<td>2</td>
<td>3.3%</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>1</td>
<td>1.7%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1</td>
<td>1.7%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>1</td>
<td>1.7%</td>
</tr>
<tr>
<td>Somnolence</td>
<td>1</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

**POTENTIAL ADVERSE EVENTS**

Risks associated with the use of the PROPEL Contour sinus implant are anticipated to be similar to those experienced by patients who undergo placement of Miniclips implants or packing. Risks potentially associated with use of the PROPEL Contour sinus implant may include, but are not limited to the following:

- Premature displacement of implant or implant fragments
- Swelling of implant or implant fragments
- Pain/beyond/burst due to the adherence of crusting to, or pressure of the implant
- Aspiration of small implant fragments
- Foreign body response, including formation of granulomatous tissue
- Nasal irritation
- Hypersensitivity reaction
- Intraoral swelling
- Localized infection (bacterial, fungal, viral) in the treatment site
- Nasal furrowing
- Nasal dryness
- Vulnerability to secondary infections due to bacteria, fungi or viruses
- Glaucoma/reduction of intraocular pressure
- Osteitis/osteoitis in sinus areas
- Herpes
- Pharyngitis

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

**Symbols Used on Product Labeling**

<table>
<thead>
<tr>
<th>REF</th>
<th>Reference Number</th>
<th>Use By</th>
<th>Single Use</th>
<th>Sterilization Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LOT</strong></td>
<td>Lot Number</td>
<td>Read Instructions Prior to Use</td>
<td><strong>STERILIZED BY</strong></td>
<td>Sterilized using Irradiation</td>
</tr>
</tbody>
</table>

**Product Information Disclosure**

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