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

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.

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

PRODUCT DESCRIPTION
The PROPEL™ 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™ sinus implant contains mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. Mometasone furoate is a white to off-white powder. The chemical name is α,β-dichloro-17α-(2-furoate)-11β,16α,17α-trihydroxy-16α,17α-epoxy-1,4-α-pregnadiene-3,20-dione, with the empirical formula C27H30Cl2O6, and a molecular weight of 521.43 g/mol. Mometasone furoate is a hydrophilic drug that is practically insoluble in water. Mometasone furoate is stable under aqueous, acidic and oxidative conditions.
- The implant is bioabsorbable and is designed to accommodate 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 under endoscopic visualization. A delivery system is provided to access the ethmoid sinus and insert the implant.

PRODUCT INFORMATION
- The PROPEL™ implant is comprised of a synthetic bioabsorbable copolymer, poly-(DL-lactide-co-glycolide), PLG.
- 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.
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INDICATIONS AND INTENDED USE
The PROPEL™ sinus implant is intended for use in patients 18 years of age and older following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative interventions such as surgical adhesion lysis and/or use of steroids. The PROPEL™ sinus implant separates mucosal tissues, prevents obstruction by adhesions, and reduces edema.

CONTRAINDICATIONS
- The use of the PROPEL™ sinus implant is contraindicated in the following patients:
  - Patients with a known hypersensitivity to lactide, glycolide or caprolactone copolymers.
  - Patients with a known hypersensitivity to loctile, glycolide or caprolactone copolymers.

WARNING
- The PROPEL™ sinus implant is designed for single patient use only. Do not reprocess or reuse.
- Do not use if the package is open or damaged.

PRECAUTIONS
- Special care should be taken to avoid bending, twisting or damaging the implant.
- The implant must be placed under endoscopic visualization.
- The implant exhibits no antimicrobial properties.
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PHARMACOKINETICS
- Following bilateral drug-eluting 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 not quantifiable at any time points. Mean cortisol concentrations were within normal limits.
- The chemical structure of mometasone furoate is shown below.
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PREGNANCY
- The PROPEL™ implant is comprised of a synthetic biodegradable co-polymer, poly-(DL-lactide-co-glycolide), PLG.
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DIAGNOSIS AND ADMINISTRATION
- Each PROPEL™ implant contains 0.27 µg of mometasone furoate which is gradually released over time.

INDICATIONS FOR USE
- Insert the implant and delivery system from its protective packaging using sterile technique. Inspect for any obvious damage. ENSURE the funnel is attached to the distal end of the delivery system.
- Insert the implant by depressing the plunger while simultaneously withdrawing the delivery system.

DIRECTIONS FOR USE
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INFORMATION FOR PATIENTS
- Beggarly side effects of the implant:
  - Headache
  - Nasal obstruction
  - Nasal dryness
  - Rhinorrhea
  - Epistaxis
  - Foreign body reaction

FOREIGN BODY REACTION
- It is possible for most surgical adjuncts.
- Foreign body reaction may occur as is possible with most surgical adjuncts.
- In rare instances, the physical and chemical condition associated with sinus surgery, both with and without sinus implants or devices, may lead to a local foreign body reaction.
- Foreign body reactions to sinus implants are rare and have not been established.
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REFERENCES
In three prospective clinical trials conducted in the United States and including 205 patients, a total of 400 sinus implants, 250 were drug-eluting (243 were the 23 mm PROPEL sinus implant and 7 were a shorter version containing 220 µg of MF, available only in the pilot trial) and 150 were non-eluting control implants (143 were the 23 mm length and 7 were a shorter version containing 22, and TNSS were statistically significant (p<0.0002).

OBSERVED ADVERSE EVENTS

The ADVANCE II trial was a prospective, randomized, double-blind, concurrent, controlled feasibility trial that enrolled 50 patients at 4 study centers. The primary efficacy endpoint was the induction in need for post-operative interventions at day 30, determined from video-endoscopies reviewed by an panel of independent blinded sinus surgeons. Post-operative or intervention was required to separate an adhesion and/or site related intervention to resolve recurrent ethmoid sinus inflammation, edema or polyoid recurrence. Additional efficacy endpoints were determined by endoscopic grading done by clinical investigators at the study centers.

The primary safety endpoint was ocular safety defined as absence of clinically significant sustained elevation (≥10 mm Hg) in intraocular pressure through Day 90. Ocular examinations also included assessment of change in or development of lens opacities.

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

**Symptoms Used on Product Labeling**

**Use of this product in a method may be covered by one or more of U.S. Patent Nos. 7,544,192, 7,662,141, 7,662,142, 7,713,255, 7,951,130, 7,951,131, and 7,951,133. Other United States and Non-United States Patents Pending.**

**Post-Operative Care:**

- As part of routine post-operative care, frequent use of saline sprays, drops or irrigation is recommended to keep the implant moist.
- Routine debridement may be performed as part of the usual post-operative care.
- The implant may be removed at the discretion of the physician by use of suction, forceps or other surgical instruments.

**CLINICAL TRIALS**

The efficacy and safety of the PROPEL implant, when used in adult patients with chronic or sinus mucosal, underlying functional endoscopic sinus surgery (FESS), have been studied in three prospective clinical trials conducted in the United States and involving 205 patients. The primary safety and efficacy information is derived from the ADVANCE I clinical trial and is supported by the ADVANCE II pilot study. In all these studies, implant placement occurred following endoscopic sinus surgery. Implants were placed in a total of 400 subjects in the 205 patients. Of the 400 implants, 16 (4%) were removed and replaced immediately after deployment due to sub-optimal apposition, inverted studs or inadvertent removal and 3 (0.8%) were damaged during preparation. In these 3 cases, new implants were used successfully.

The ADVANCE I study was a prospective randomized, double-blind, concurrently controlled study that enrolled 105 patients at 11 study centers. The study utilized an intra-patient control design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-inflamed portion of the control implant. The primary efficacy endpoint was the induction in need for post-operative interventions at day 30, determined from video-endoscopies reviewed by an panel of independent blinded sinus surgeons. Post-operative or intervention was required to separate an adhesion and/or site related intervention to resolve recurrent ethmoid sinus inflammation, edema or polyoid recurrence. Additional efficacy endpoints were determined by endoscopic grading done by clinical investigators at the study centers.

The CONSENSUS II pilot study was 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 intra-patient control design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-inflamed portion of the control implant. The primary efficacy endpoint was the induction in need for post-operative interventions at day 30, determined from video-endoscopies reviewed by an panel of independent blinded sinus surgeons. Post-operative or intervention was required to separate an adhesion and/or site related intervention to resolve recurrent ethmoid sinus inflammation, edema or polyoid recurrence. Additional efficacy endpoints were determined by endoscopic grading done by clinical investigators at the study centers.

The primary safety endpoint was ocular safety defined as absence of clinically significant sustained elevation (≥10 mm Hg) in intraocular pressure through Day 90. Ocular examinations also included assessment of change in or development of lens opacities.

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