PROPEL® Mini with Straight Delivery System
(mometasone furoate implant, 370 µg)

Instructions For Use

PROPEL® Mini 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® Mini 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 9α-[21-dichloro-17β-(3β,17β-dihydroxy-16a,17a-ethylenedioxy)-19(11)H-pregna-5,16-diene-3,20-dione 17-(2-furoate), with the empirical formula C27H30Cl2O6, and a molecular weight of 521.43 g/mol. Mometasone furoate is a hydrophilic, polyether, and polyethylene glycol.

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® Mini Sinus Implant is comprised of a synthetic bioabsorbable co-polymer, poly-(DL-lactide-co-glycolide), PLG.

The PROPEL® Mini 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® Mini Sinus Implant with Straight Delivery System is intended for use in patients ≥18 years of age following endoscopic sinus surgery to maintain patency of the ethmoid sinus. The PROPEL® Mini Sinus Implant is not intended to be used for anatomical correction of the middle turbinate, prevention of postoperative bleeding, or reduction ofhoemorrhage. The implant reduces the need for post-operative intervention such as surgical resection of the osteomeatal unit.

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.

Indications and Intended Use
The PROPEL® Mini Sinus Implant with Straight Delivery System is indicated for use in patients ≥18 years of age following endoscopic sinus surgery to maintain patency of the ethmoid sinus.

Contraindications
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.
- Patients with known hypersensitivity and/or intolerance to lactide, glycolide or caprolactone copolymers.

Warnings
- The PROPEL® Mini 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.
- 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 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 antiretroviral properties.
- The implant should not be used with mucosal surgical adjuncts.
- The implant should not be used in patients with sinus surgical history.
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Drug Interactions
No drug-drug interaction studies have been conducted with the implant.

Carcinogenicity, Genotoxicity and Reproductive Toxicity
No long-term studies in animals have been performed to evaluate the carcinogenic potential of the implant.

Pregnancy
Pregnancy and Nursing Females: The safety and effectiveness of the implant in pregnant or nursing females have not been established.

Pediatric Use: The safety and effectiveness of the implant in pediatric patients have not been established.

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.

Post-operative Care
- As a part of post-operative care, frequent use of saline sprays, rinses 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.

DOSAGE AND ADMINISTRATION
Each PROPEL® Mini implant contains 370 µg of mometasone furoate which is gradually released over time.

DIRECTIONS FOR USE
1. Rinse 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.
3. Ensure that the delivery system is oriented so the distal tip is angled superiorly toward the posterior roof of the sinus cavity.
4. Align the distal tip of the delivery system with the anterior edge of the middle turbinate.
5. Insert the implant by depressing the trigger while simultaneously withdrawing the delivery system.
6. 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.

CAUTION: Do not leave the PROPEL® Mini implant in the crimped state for more than 5 minutes prior to placement.

The implant may be compressed the second time using the crimping by expanding the belt inside the crimper and repeating the steps above.

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Intranasal Instructions For Use

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 (ESS), have been studied in three prospective clinical trials conducted in the United States and involving 305 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 study. In all three studies, implant placement occurred following phonoscopy. Implants were successfully placed in a total of 96% across the 205 patients. Of the 59 implants, 16% were removed and replaced immediately after deployment due to sub-optimal apposition, closure of wounds or treatment removal, and 3 (0.8%) were damaged during deployment. In these 3 cases, a new implant was used successfully.

The ADVANCE II study was a prospective randomized, double-blind, concurrently controlled study that enrolled 115 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-surgical control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative interventions at Day 30, determined from video-endoscopies reviewed by a panel of independent blinded surgeons. Post-operative intervention was a procedure intended to exclude surgical interventions required to separate an adhesion and/or implant erosion to resolve recurrent ethmoid sinus inflammation, sinonasal and/or polyp recurrence. A lower rate of adverse events was determined by endoscopic grading done by clinical investigators at the study centers. The primary safety endpoint was a serious adverse event. The PROPEL® implant delivery success rate was 100%. The primary efficacy endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 30 (p=0.69). There were no clinically significant increases in intraoperative and postoperative adverse events from baseline to no operations.

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