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 50°F) with excursions permitted to 15-30°F. 

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

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

PRODUCT DESCRIPTION
The PROPEL® 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 16α,21-dihydroxy-11β-(4a-ethylthio-1a,4a-diene-3β,20-dione-17α)-21-ol, with the molecular formula C21H25O2S and a molecular weight of 321.43 g/mol. Mometasone furoate is a hydrophobic drug that is practically insoluble in water. Mometasone furoate is stable under aqueous, acidic and oxidative conditions. It is biodegradable under extreme basic, thermal and photolytic conditions. The chemical structure is shown below. The drug is embedded in a bioabsorbable polymer matrix consisting of (DL-lactide-co-glycolide) and polyethylene glycol (narrowing agent) which provides gradual release of the drug.

The active 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.

Chemical structure of poly(DL-lactide-co-glycolide)
Chemical structure of polyethylene glycol

Implant Component Description
The PROPEL® implant is comprised of a synthetic bioabsorbable co-polymer, poly(DL-lactide-co-glycolide) PLG.

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.

Contraindications
The PROPEL® sinus implant is contraindicated in the following patients:

- Patients with suspected or confirmed intolerance to mometasone furoate.
- Patients with a known hypersensitivity to lactide, glycolide, or copolymers of lactide and glycolide.

Warnings
- The PROPEL® sinus implant is designed for single patient use only. Do not reprocess or reuse.

Precautions
- Do not use if the package is open or damaged.

Drug Interactions
No drug-drug interactions 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
There have been no controlled studies in pregnant women using the PROPEL® sinus implant. The PROPEL® sinus implant should not 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® implant should be used only if the potential benefits justify the potential risk.

Dosage and Administration
Each PROPEL® implant contains 370µg of mometasone furoate which is gradually released over time.

Direction for Use
1. Unpack 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. Confirm the implant is well apposed to the tissue to maximize drug delivery. Do not use if the package is open or damaged.
3. Confirm the position of the implant and delivery system tip to tip. To adjust the position of the implant and delivery system...

Predications
- Do not leave the PROPEL® implant in the crimped state for more than three minutes prior to placement.
- Confirm the proximal loops of the implant align with the anterior edge of the middle turbinate.
- Confirm the proximal loops of the implant align with the anterior edge of the middle turbinate (see illustration below).
- Confirm the implant is well apposed to the tissue to maximize drug delivery.

Adjust the position of the implant and delivery system.

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IFU 00340 Rev D
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CLINICAL TRIALS

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 205 patients. The primary safety endpoint was ocular safety defined as absence of clinically significant sustained elevation (≥10 mm Hg) in intraocular pressure in through Day 49. Coarse rhinosinusitis was also included assessment of changes in or development of lesions opacified.

The PROPEL® implant safety rate was 105%. The primary efficacy endpoint was to demonstrate a statistically significant reduction in the need for post-operative interventions at day 30 (p < 0.008). There were no clinically significant increases in intracranial pressure and no significant changes from baseline in lesions opacified.

The PROPEL® implant delivery success rate was 104%. The primary efficacy endpoint was to demonstrate a statistically significant reduction in the need for post-operative interventions at day 30 (p < 0.008). There were no clinically significant increases in intracranial pressure and no significant changes from baseline in lesions opacified.

ADVERSE EVENTS

OBESERVED ADVERSE EVENTS

In three prospective clinical trials conducted in the United States and including 205 patients, a total of 455 implants were studied. Of these 455 implants, 205 were drug-eluting (104) were the 23 mm PROPEL® sinus implant and 7 were a shorter version containing 200 μg of MF. The overall incidence rate of study-related adverse events was 45%.

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

- nasal irritation
- sneezing
- rhinorrhea
- epistaxis
- sinusitis
- allergic reactions
- candidiasis
- glucocorticoid-induced intraocular pressure
- cataractogenesis changes in lens opacities
- myopia

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

Symbols Used on Product Labeling

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Product Information Disclosure

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Use of this product is a medical device covered by one or more of U.S. Patent Nos. 7,544,150; 7,662,141; 7,642,142; 7,713,255; 7,651,193; 7,631,913; and 7,681,133.

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