PROPEL® Mini
(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 25º C) with excursions permitted to 15-30º 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.
- Do not use if the package is open or damaged.
- The PROPEL Mini Sinus Implant is designed for single patient use only. Do not reprocess or reuse.

PRODUCT DESCRIPTION

The 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 C21H30O5[CH2COCH2CH(CH3)2] and its molecular weight is 321.45 g/mol. Mometasone furoate is soluble under aqueous, acidic, and acidic conditions. Mometasone furoate can degrade under extreme basic, thermal and photolytic conditions. The chemical structure is shown below. The drug is embedded in a bioabsorbable polymer matrix containing poly(DL-lactide-co-glycolide) and polyethylene glycol (water-soluble) which provide for gradual release of the drug.

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

- Pregnant women or women nursing within 6 months of delivery, and those who may become pregnant during treatment. Mometasone furoate cannot penetrate the placenta, therefore no data are available on its effects on pregnancy outcomes. Pregnant women are advised to use reliable contraception, and to discontinue treatment before conception.
- Patients with a known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with suspected or confirmed intolerance to mometasone furoate.
- Nursing women.

WARNINGS:

- The PROPEL Mini implant is designed for single patient use only. Do not use if the package is open or damaged.

INDICATIONS AND USE:
The PROPEL® Mini Sinus Implant is intended for use in patients ≥ 18 years of age following endoscopic endonasal sinus surgery for chronic sinusitis and subsequent weekly morning blood sampling for 4 weeks in 5 adult patients.

MECHANISM OF ACTION:
Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, neutrophils, monocytes, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. The precise mechanisms behind the anti-inflammatory properties of the ester mometasone furoate is not known.

PRECAUTIONS:

- Special care should be taken to avoid bending, twisting or damaging the implant.
- The implant is not intended to be modified by the physician.
- Special care should be taken to avoid bending, twisting or damaging the implant.
- The implant exhibits no antimicrobial properties.
- Foreign body reaction may occur in a patient with a sinus implant.
- The implant must not be placed under endoscopic visualization.

STORAGE:

The PROPEL® Mini Sinus Implant is intended for use in patients ≥ 18 years of age following ethmoid/frontal sinus surgery. The implant is designed for single patient use only. Do not reprocess or reuse. The implant is not intended to be compressed and loaded into the delivery system more than two times.

DOSAGE AND ADMINISTRATION:
The PROPEL® Mini Sinus Implant is intended for use in patients ≥ 18 years of age following ethmoid/frontal sinus surgery. The implant is designed for single patient use only. Do not reprocess or reuse.

1. Insertion of the implant and delivery system from the post-operative pack to insertion into the delivery system:
   - Insert the implant by depressing the pusher while simultaneously withdrawing the delivery system.
   - The implant may be compressed and loaded into the delivery system up to two times. The implant may be compressed the second time using the crimper (by expanding the belt inside the crimper and repeating the steps above).
   - Use the loading tool to push the stent past the opening of the funnel.
   - Gently remove the compressed stent from the crimper with three fingers.
   - Insert compressed implant into the funnel attached to the distal tip of the delivery system.
   - Use the loading tool to push the stent past the opening of the funnel.
   - Carefully remove the funnel, taking care not to dislodge the implant from the tip of the delivery system. If the implant dislodges during funnel removal, replace the funnel and use the loading tool to push the implant back into the delivery system.
   - Do not use standard surgical instruments.
   - Remove the implant from the delivery system after filling the cavity and before the implant is fully deployed.
   - After insertion, the implant should be visible at the ostium.

Other Components Available:
The PROPEL Mini Straight Delivery System (5-packs) is sold and packed separately as an alternative option for ethmoid sinus access and implant delivery. The 5-pack includes:
- Delivery System Length = 16 mm
- Funnel & Stent = 5
- Crimper, Loading Tool, Funnel, Funnel Loading Tool, Delivery System Length = 110 mm

Product is supplied sterile and for single use only.

PRINCIPAL CONCERNS:
The PROPEL Sinus Implant underwents pharmacokinetic testing. Following oral drug-regulating PROPEL implant placement other 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 point. Mean cortisol concentrations were within normal limits.

DRUG-INTERACTIONS:

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.

Dosage:
Children: 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.

Some corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, monocytes, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. The precise mechanisms behind the anti-inflammatory properties of the ester mometasone furoate is not known.

Additional References:

This product should be stored at room temperature (approximately 25º C) with excursions permitted to 15-30º C. Sterilized by irradiation. Do not use if the package is open or damaged.

Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, neutrophils, monocytes, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. The precise mechanisms behind the anti-inflammatory properties of the ester mometasone furoate is not known.

The implant exhibits no antimicrobial properties.

Foreign body reaction may occur in a patient with a sinus implant.

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

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

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650-641-2100    Page 1 of 2

Intersect ENT Inc.
1555 Adams Drive
Menlo Park, CA 94025
650-641-2100
CustomerService@intersectENT.com
IFU 00341 Rev P
Page 1 of 2
CLINICAL TRIALS
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Primary efficacy endpoint was the reduction in need for post-operative sinus intervention assessed by independent blinded sinus surgeons.

Secondary endpoint was safety and efficacy of the PROPEL Mini Sinus Implant when placed following surgery on one sinus side compared to the non-drug control version of the implant.

Evaluation of adverse events was conducted for all patients who received at least one dose of the study treatment during the study phase. The relationship between PROPEL® Mini Sinus Implant and a concomitant event was determined by an independent blinded sinus surgeon based on video-endoscopy review.

The PROPEL® Mini Sinus Implant was safe and well tolerated. The most common adverse events were headache, nasal burning, and sinusitis.

Risks associated with the use of the PROPEL Sinus Implant are anticipated to be similar to those associated with the use of systemic corticosteroids.

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