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

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE

STORAGE
Store to avoid moisture. Do not use if package is open or damaged.

STABILITY
The product should be stored at room temperature (15° to 30°C) with excursions permitted to 5° to 30°C.

SINGLE USE
Prepunched tip is 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® Contour sinus implant provides sustained release of mometasone furoate via a biodegradable 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 6x,21-bis(chloro-1,1,1- trifluoro-methyl)-17x,21-dihydroxy-16α,17α-methyleneprogesterone furoate. The drug is available as a hydrodestilled drug form (11x,21-dihydroxy-16α,17α-methyleneprogesterone furoate) in water. Mometasone furoate is stable under aqueous acid and saline conditions. Mometasone furoate can degrade under extreme basic, chemical and photostatic conditions. This chemical structure is shown below. The drug is embedded in a biodegradable polymer matrix containing poly(D,L-lactic-co-glycolide) and polyethylene glycol (PEG) (inactive ingredients) which provides for gradual release of the drug.

The inactive ingredients on the sinus implant are poly(D,L-lactic-co-glycolide) and polyethylene glycol. Poly(D,L-lactic-co-glycolide) is an amorphous biodegradable polymer. The chemical structure is shown below.

Polyethylene glycol is a hydrophilic polymer compound that is highly flexible. It is non-toxic and non-immunogenic. The chemical structure is shown below.

Implant Component Description
The PROPEL® Contour sinus implant is comprised of a biodegradable co-polymer, poly(D,L-lactic-co-glycolide), PEG, and a drug component. The implant is biodegradable and is designed to accommodate the size and variability of the surgically enlarged frontal or maxillary sinus. Once inserted, the implant is designed to be self-releasing 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 handled by a physician under endoscopic visualization. A delivery system is provided to access the frontal or maxillary sinus ostium and deploy the implant. A loading tool and funnel are optional accessories provided to assist in the loading of the implant into the delivery system.

INDICATIONS AND INTENDED USE
The PROPEL® Contour sinus implant is intended for use in patients 16 years of age to maintain patency of the frontal and maxillary sinuses following sinus surgery and locally deliver steroids to the sinus mucosa. The PROPEL® Contour sinus implant exerts pharmacologic effects on mucous tissues, inflammation, perineural extension by adherence/clogging, and reduces exudate. The implant reduces the need for repeat intervention such as surgical debridement and/or use of steroids.

CONTRAINDICATIONS
The use of the PROPEL® Contour sinus implant is contraindicated in the following patients:
- Patients with suspected or confirmed instances to mometasone furoate.
- Patients with known hypersensitivity to lactic acid, glycolic acid or caprolactic copolymers.

WARNINGS
- The PROPEL® Contour sinus implant is designed for single-patient use only. Do not resupersise or reuse.
- Do not re-use if the package is open or damaged.

PRECAUTIONS
- The implant should be handled by a physician under endoscopic visualization. A delivery system is provided to access the frontal or maxillary sinus ostium and deploy the implant. A loading tool and funnel are optional accessories provided to assist in the loading of the implant into the delivery system.

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

PHARMACOKINETICS
The PROPEL® Sinus Implant undergoes pharmacokinetic testing. Following bilateral drug guiding of 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 not quantifiable at any time point. Mean cortisol concentrations were within normal limits.

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.

FREQUENCY
There have been no controlled studies in pregnant women using the PROPEL® Contour sinus implant. The PROPEL® Contour sinus implant should 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 implant should be used only if the potential benefits justify the potential risk.

DOSAGE AND ADMINISTRATION
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. Impact for any obvious damage.
2. Place the implant in the delivery system.
3. a) Using your fingers, gently bend top of the applicator to the desired angle while supporting the tubing with your fingers. The usable range of the delivery system is from 70° to 110° degrees.
    b) Release the plunger.

Step 2a

Step 2b

Step 3a

Step 3b

Step 3c

Step 3d

Step 3e

Step 3f

Step 3g

Step 3h

Step 3i

Step 3j

Step 3k

Step 3l

Step 3m

Step 3n

Step 3o

Step 3p

Step 3q

Step 3r

Step 3s

Step 3t

Step 3u

Step 3v

Step 3w

Step 3x

Step 3y

Step 3z

Step 4

Step 4a

Step 4b

Step 4c

Step 4d

Step 4e

Step 4f

Step 4g

Step 4h

Step 4i

Step 4j

Step 4k

Step 4l

Step 4m

Step 4n

Step 4o

Step 4p

Step 4q

Step 4r

Step 4s

Step 4t

Step 4u

Step 4v

Step 4w

Step 4x

Step 4y

Step 4z

CAUTION
- Do not leave the implant in the crimped exterior more than three minutes prior to placement.

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4. For adequate visualization, use hemorrhoids in operated sinus septa and/or cavities prior to insertion. Advance the delivery system into the sinus cavity using endoscopic visualization.

5. To insert implant in the sinus cavity:
   a. Ensure the delivery system is seated on the sinus cavity appropriately for the largest patient anatomy and advance distal tip of the delivery system into the sinus cavity.
   b. Note: The markings (open arrow) on the distal end of the delivery system may be used as a fiduciary (for reference only).
   c. Deploy the implant thereby deploying the plunger until the distal edge of the colored pusher aligns with the lens to cease transition. At this point, the implant is approximately halfway deployed.
   d. Gently withdraw the delivery system to evaluate the width of the implant (which is defined by the distal cross-sections).
   e. Align the widest of the implant with the sinus.
   f. While holding the distal tip of the delivery system, continue withdrawing the delivery system from the sinus cavity while simultaneously constricting to depress the plunger.
   g. Maintain a 90° angle between the implant and the sinus cavity.
   h. Confirm implant placement by endoscopic visualization. Confirm the width of the implant is aligned with the sinus cavity. Confirm the implant is well-applied to the tissue to maximize drug delivery. To adjust the position of the implant, use standard endoscopic instruments.

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 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 safety and efficacy of the PROPEL Contour sinus implant when placed in the maxillary sinus ostia (MISO) and frontal sinus ostia (FSO) following endoscopic sinus surgery (ESS) in patients with chronic sinusitis was assessed in 2 prospective clinical trials conducted in the United States.

The EXCEED study was a prospective, single-arm, open-label, feasibility trial designed to assess the performance, safety and initial signals of efficacy of the PROPEL Contour sinus implant placement in the frontal and maxillary sinuses in patients with chronic sinusitis following ESS in the frontal and maxillary sinuses. Fifteen of 16 patients enrolled at 2 study sites were eligible to participate. The EXCEED study results showed an overall implant delivery success rate of 97.1% (15/16 in frontal sinus; 96.9% in maxillary sinuses), demonstrating that the primary performance endpoint was met. No serious unanticipated AEs were reported; therefore, the study met the primary safety endpoint. In addition, no AEs were related to placement of the PROPEL Contour sinus implant. Observed endoscopic improvements at Day 30 included a 48.9% increase in polypoid polyps, a 70.1% reduction in polypoided sinuses, a 19% reduction in grade 3 and grade 4 adhesion scoring, and a 3.6% decrease in inflammatory scores. The mean SWT 224 acute at Day 8 showed a treatment-effect size of 1.09, representing a large health benefit. None of the patients required stand-by for sinus obstruction, and only 2 received surgical intervention (i.e., polypectomy, removal of left frontal sinus) through the duration of the study.

The PROGRESS study was a prospective, randomized, blinded, controlled study that enrolled 80 patients across 12 study centers. The study utilized an intention-to-treat design to assess the safety and efficacy of the PROPEL Contour sinus implant following surgery in 1 sinusal cavity compared to surgery alone in the contralateral side. The primary efficacy endpoint was the reduction in need for post-operative interventions at Day 30, as determined by an independent, blinded, sinus surgeon based on endoscopic recurrence of health-related symptoms (i.e., if post-operative interventions were unanticipated events that indicated surgical intervention required to debulk residual adhesions or re-tissue formation grade 2 or grade 3 or the frontal sinus ostia, and/or sinus-related pain associated with residual ostial disease). The PROGRESS study demonstrated that the PROPEL Contour sinus implant is well-tolerated by all patients, with no serious unanticipated AEs. No patients withdrew from the study due to adverse events, and no deaths occurred. The study results showed a statistically significant reduction in the need for post-operative interventions (p = 0.0022) and a statistically significant increase in quality of life (p = 0.0012) observed at 12 weeks and 24 weeks follow-up by the PROPEL Contour sinus implant at the distal tip is delivered into the sinus cavity via the delivery system and the implant is self-deployed. The PROPEL Contour sinus implant is constructed of high-density polyethylene (HDPE) and contains a drug (mometasone furoate) and is designed to deliver a 370 μg dose of the drug over 12 months. The implant may be used in patients who have undergone sinus surgery and are at risk for polypoid eosinophilic adenoid hypertrophy.

ADVERSE EVENTS

OBSERVED ADVERSE EVENTS

PROPEL Contour sinus implants are actively releasing siamines in sinus cavities that are smaller than the PROPEL Mini to accommodate the size and variability of the implanted siamines. Two prospective clinical trials (EXCEED and PROGRESS) conducted in the United States studied 66 patients and 125 PROPEL Contour sinus implants. In the EXCEED study, no implant-related serious adverse events were reported, resulting in a 0% incidence rate of implant-related adverse events. No patients withdrew due to an adverse event, and no deaths occurred.

In the Novus cohort (with PROPEL Contour), the PROGRESS study with 86 patients, no implant-related serious adverse events or adverse events were observed, resulting in a 0% overall incidence rate of implant-related adverse events. Three adverse events (nasal irritation, rhinorrhea, and rhinitis) were reported as adverse events related to implant use. No patients withdrew due to an adverse event and no deaths occurred. Adverse events are defined as the presence of any clinical investigation finding that may cause patient discomfort or impact patient function (regardless of relationship to implant), which were reported in 2 or more patients in PROPEL Contour study in the summary table below.

POTENTIAL ADVERSE EVENTS

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

- Prevalence of implant or implant fragments
- Swelling of implant or implant fragments
- Pain/painful headache due to the adherence of suturing to or presence of the implant
- Nasal irritation
- Swelling of implant or implant fragments
- Foreign body reaction, including formation of granulation tissue

Roles potentially associated with interventional mammalian functions may include, but not limited to the following:

- Nasal irritation
- Hypersensitivity reaction
- Infection (contamination or infection)
- Nasal obstruction (e.g., nasal septum, nasal cavity, or naso-cranial tunnel, including, but not limited to xerosis, nasal polyps or polypoid adenoid hypertrophy)
- Nasal dryness
- Susceptibility to secondary infections due to bacteria, fungus or virus
- Granulation tissue formation in the nasal cavity
- Granulation tissue formation in the sinus cavity
- Headache

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

Symbols Used on Product Labeling

REF: Reference Number
Lot Number
Use By
Read Instructions Prior To Use
Single Use
Sterilized using Irradiation

Product Information Disclosure

International ENT, Inc. has not established a reasonable care in the manufacture of this product. International ENT, Inc. excludes all warranties, whether expressed or implied, by operation of law or otherwise, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose, in connection with the use, misuse or non-use of this product, as well as in relation to this product, diagnosis, treatment, surgical procedure or any other matter related to International ENT, Inc. to the extent allowed by this product. All liability from use of International ENT, Inc. shall not be held for any incident or consequential, damage in express, directly or indirectly arising from the use of this product. International ENT, Inc. neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with the product, use, and/or sale of this product.

Use of this product in a method may be covered by one or more of U.S. Patent Nos. 7,544,192, 7,682,161, 7,682,162, 7,711,235, 7,705,130, 7,705,131, and 7,886,113. Other United States and Non-United States Patents Pending.

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