PHARMACOKINETICS: The PROPEL Sinus Implant underwent pharmacokinetic testing. Following bilateral drug-eluting PROPEL Sinus Implant placement in the ethmoid or frontal sinus, each implant is designed to prevent obstruction by post-surgical adhesions and reduce inflammation, thereby reducing the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.

INDICATIONS AND INTENDED USE

MECHANISM OF ACTION: Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. The precise mechanism behind the anti-inflammatory properties of the esterified mometasone furoate is unknown.

CAUTION:

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

DRUG INTERACTIONS

No drug-drug interaction studies have been conducted with the implant.

DOSAGE AND ADMINISTRATION

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

DIRECTIONS FOR USE

1. Ensure that the delivery system is oriented so the distal tip is curved superiorly toward the posterior roof of the sinus cavity.
2. Use standard surgical instruments.
3. To insert the implant in the frontal sinus:
   a. Ensure that the delivery system is aligned with the anterio r orbital rim.
   b. The implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and prevent post-surgical adhesions.
4. To insert the implant in the frontal sinus:
   a. Ensure that the delivery system is aligned with the anterior orbital rim.
   b. Confirm final placement by endoscopic visualization.
   c. The implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and prevent post-surgical adhesions.

DOSAGE AND ADMINISTRATION

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

DIRECTIONS FOR USE

1. Use standard surgical instruments.
2. To insert the implant in the frontal sinus:
   a. Confirm final placement by endoscopic visualization.
   b. The implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and prevent post-surgical adhesions.
3. To insert the implant in the frontal sinus:
   a. Confirm final placement by endoscopic visualization.
   b. The implant is designed to be self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and prevent post-surgical adhesions.

PRINCIPAL ADVERSE EVENTS:

i. Nasal irritation
ii. Hemorrhage
iii. Local post-operative infection
iv. Foreign body reaction may occur as is possible with most surgical adjuncts.

Foreign body reaction may occur as is possible with most surgical adjuncts.

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Foreign body reaction may occur as is possible with most surgical adjuncts.
**CLINICAL TRIALS**

PROPEL® Mini is a smaller version of the PROPEL Sinus Implant. The efficacy and safety of the PROPEL® Mini, when used in adult patients with chronic sinusitis undergoing functional endoscopic sinus surgery (FESS), has been studied in three prospective clinical trials conducted in the United States and totaling 205 patients. The principal safety and efficacy information is derived from the ADVANCE clinical trial and CONSENSUS II pilot study; in all the studies, implant placement occurred without rhinotomy. Implants were successfully placed in a total of 409 sinuses in the 205 patients. Of the 409 implants, 16 (4%) were removed and replaced immediately after placement due to sub-optimal apposition, crossed stents or irreversibly deformed stents during preparation. In these 16 cases, a new implant was used without modification.

The ADVANCE study was a prospective, randomized, double-blind, concurrently controlled study that enrolled 105 patients at 11 study centers. The study utilized an intranasal control design to assess the safety and efficacy of the drug-eluting PROPEL® Mini implant compared to the non-drug-eluting control implant. The primary safety endpoint was ocular adverse events defined as clinically significant elevation greater than or equal to 10 mm Hg in intraocular pressure through Day 30. Ocular adverse events were also included in the ITT population but were only evaluated at the 30-day visit. Ocular adverse events were defined as severe if they continued after the 30-day visit.

The CONSENSUS II pilot study was a prospective, randomized, double-blinded, concurrently controlled study that enrolled 80 patients at 11 study centers. The study utilized an intranasal control design to assess the safety and efficacy of the drug-eluting PROPEL® Mini implant when placed after surgery on one side compared to surgery on the contralateral side with the control implant. The primary safety endpoint was ocular adverse events defined as clinically significant elevation greater than or equal to 10 mm Hg in intraocular pressure through Day 30. Ocular adverse events were also evaluated at Day 30.

The PROGESS study was a prospective, randomized, double-blind, controlled study that enrolled 59 patients at 11 study centers. The study utilized an intranasal control design to assess the safety and efficacy of the drug-eluting PROPEL® Mini implant following functional endoscopic sinus surgery (FESS) and revision surgery on the contralateral side with the control implant. The primary safety endpoint was ocular adverse events defined as clinically significant elevation greater than or equal to 10 mm Hg in intraocular pressure through Day 30.

The PROPEL® Mini implant was placed in the frontal sinus opening (FSO) following frontal sinusotomy and sinus speculum placement at the study centers. The advancement of the anti-inflammatory agent, fluticasone propionate, was demonstrated to achieve high local concentrations at the sinus ostium.

### ADVERSE EVENTS

#### OBSERVED ADVERSE EVENTS

**ADVERSE EVENTS FROM THE PROPEL® MINI SINUS IMPLANT**

**All 5 events resolved without sequelae. No patients withdrew due to an adverse event and no deaths occurred in this trial.**

### POTENTIAL ADVERSE EVENTS

**Note:** Events were tabulated through Day 60 in the feasibility trial and Day 90 in the two clinical trials. Risks associated with the use of the PROPEL Sinus Implant are anticipated to be similar to those associated with the use of all sinus implants and procedures. Potential adverse events are listed below. These adverse events are generally predictable, non-alarming, and manageable. Ocular adverse events and adverse events related to sinus infection are discussed in detail in the INSTRUCTIONS FOR USE. All adverse events and adverse events related to sinus infection are discussed in detail in the INSTRUCTIONS FOR USE.

**Symbols Used on Product Labeling**

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