2. The implant must be compressed and loaded into the tip of the delivery system prior to use.

**DIRECTIONS FOR USE**

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

**DOSAGE AND ADMINISTRATION**

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

**PREGNANCY**

No long term studies in animals have been performed to evaluate the carcinogenic potential of the implant.

**DRUG INTERACTIONS**

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

**DRUG INFORMATION**

The PROPEL implant is not designed to be modified by the physician.

**CONTRAINDICATIONS**

The use of the PROPEL sinus implant is contraindicated in the following patients:

- Patients with a known hypersensitivity and/or intolerance to lactide, glycolide or caprolactone copolymers.
- Patients with suspected or confirmed hypersensitivity and/or intolerance to mometasone furoate.
- Pregnant or nursing females: the safety and effectiveness of the implant in pregnant or nursing females have not been established.

**WARNING**

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

**INDICATIONS AND INTENDED USE**

The PROPEL® sinus implant is provided to insert the implant. A delivery system is provided to insert the implant.

**Implant Component Description**

The PROPEL® implant is a bioabsorbable sinus implant. The implant is designed to accommodate the size and variability of the post-surgical ethmoid sinus anatomy. Once inserted, the implant is designed to self-retaining against the mucosa of the surgically enlarged sinus in order to maintain sinus patency and deliver drug to the mucosa. The implant is intended 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 use of the PROPEL® implant is contraindicated in the following patients:

- Patients with a known hypersensitivity and/or intolerance to lactide, glycolide or caprolactone copolymers.
- Pregnant or nursing females: The safety and effectiveness of the implant in pregnant or nursing females have not been established.

**PRECAUTIONS**

- Special care should be taken to avoid bending, twisting, or damaging the implant.
- The implant is not designed to be modified by the physician.
- The implant must be placed under endoscopic visualization.
- The implant exhibits no antiretroviral properties.
- Foreign body reaction may occur as is possible with most surgical adjuncts.
- Allergic reactions have been observed in patients using the PROPEL sinus implant.
- The implant is intended 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 implant should be used only if the potential benefits justify the potential risk.

**DOSEAGE AND ADMINISTRATION**

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

**DIRECTIONS FOR USE**

1. Ensure 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. For adequate visualization, ensure hemostasis in operated sinus cavities prior to insertion. Advance the Delivery System into the sinus cavity using endoscopic visualization. To insert the implant:

   a. Ensure that the Delivery System is oriented so the distal tip is curved superiorly toward the posterior roof of the sinus cavity.
   b. Align the proximal end of the implant with the anterior edge of the middle turbinate.
   c. Insert the compressed implant into the funnel attached to the distal tip of the delivery system.
   d. Gently push the implant into the funnel (see as possible) using a finger tip.
   e. Carefully remove the funnel, taking care not to dislodge the implant from the tip of the delivery system. If the implant begins to withdraw from the tip during funnel removal, replace the funnel and gently squeeze the tip of the delivery system to hold implant in place.

   CAUTION: Do not leave the PROPEL® implant in the compressed state for more than three minutes prior to placement.

   f. The implant may be compressed and loaded into the delivery system tip up to two times.

   a. Gently slide implant off its holder.
   b. Grasp the implant between the fingers of both hands and gently compress the implant.
   c. Insert the implant by depressing the plunger while simultaneously withdrawing the delivery system.
   d. Align the proximal end of the implant with the anterior edge of the middle turbinate (see illustration below). Confirm the implant is well apposed to the tissue to maximize drug delivery. To adjust the position of the implant, use standard surgical instruments.

   e. Carefully remove the funnel, taking care not to dislodge the implant from the tip of the delivery system. If the implant begins to withdraw from the tip during funnel removal, replace the funnel and gently squeeze the tip of the delivery system to hold implant in place.

   Step 2b
   Step 2c
   Step 2d
   Step 2e

4. Confirm final placement by endoscopic visualization. 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. To adjust the position of the implant, use standard surgical instruments.

5. Confirm final placement by endoscopic visualization.
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 and efficacy information is derived from the ADVANCE I clinical trial and is included in the CONSENSUS II pilot study. In all three studies, implant placement occurred following sinonasal endoscopy. Implants were successfully placed in a total of 400 sinuses in the 205 patients. Of the 400 implants, 16 (4%) were removed and replaced immediately after deployment due to suboptimal apposition, excess strut or bend removal and 3 (0.8%) were damaged during preparation. In these 3 cases, new implants were used successfully.

The ADVANCE I study was a prospective randomized, double-blind, concurrently controlled feasibility trial that enrolled 105 patients at 11 study centers. The study evaluated an intranasal control trial to assess the safety and efficacy of the PROPEL sinus implant compared to the non-porous 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 sinus surgeons. Post-operative intervention was defined as any intervention required to separate an adhesion and/or site of delayed retraction to restore the mucosal lining, edema or polyopy inflammation. Additional efficacy endpoints were determined by endoscopic grading done by clinical investigators at the study centers.

The primary safety endpoint was ocular safety defined as an absence of clinically significant sustained (10 mm Hg) intraocular pressure through Day 90. Ocular examinations also included assessment of changes in or development of lens opacities.

The PROPEL sinus implant is a medical device. The primary safety and efficacy results from the ADVANCE I clinical trial showed no clinically significant increase in intraocular pressure and no clinically significant changes from baseline in lens opacities.

CLINICAL SAFETY RESULTS

Of the 400 implants, 16 (4%) were removed and replaced immediately after deployment due to suboptimal apposition, excess strut or bend removal and 3 (0.8%) were damaged during preparation. In these 3 cases, new implants were used successfully.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients at 4 centers. A total of 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version. The study utilized a non-porous intranasal control trial of saline irrigation. The primary endpoints were the reduction in sinus surgical intervention rate at postoperative day 30 and the post-operative intervention rate at Day 120 when compared to saline irrigation. The primary safety endpoints were defined as any intervention required to separate an adhesion and/or site of delayed retraction to restore the mucosal lining, edema or polyopy inflammation. Additional efficacy endpoints were determined by endoscopic grading done by clinical investigators at the study centers.

OBSERVED ADVERSE EVENTS

The risks potentially associated with use of the PROPEL implant include:

- Pain/pressure/headache may result from the adherence of crusts to, or presence of material fragments
- Epistaxis
- Intranasal bleeding
- Nasal desiccation
- Nasal obstruction
- Coughing
- Presence of small implant fragments
- Cataracts/changes in lens opacities
- Pressure
- Headache
- Pressure
- Headache
- Pressure

In the ADVANCE I study, patients randomized to the PROPEL implant arm, compared to the saline irrigation control group, had statistically significant reduction in mean total RSDI scores through Day 30 (p < 0.0001). For the SNOT 22, the changes were -1.9 and -1.7, respectively (p<0.0001). All changes from baseline in RSDI, SNOT 22 and CATS scores were statistically significant compared to baseline and the saline irrigation control group.

There were no clinically significant increases in intraocular pressure and no clinically significant changes from baseline in lens opacities.

ADVERSE EVENTS

A total of 400 implants were placed in a total of 205 patients. Of the 400 implants, 16 (4%) were removed and replaced immediately after deployment due to suboptimal apposition, excess strut or bend removal and 3 (0.8%) were damaged during preparation. In these 3 cases, new implants were used successfully.

In the ADVANCE I study, patients randomized to the PROPEL implant arm, compared to the saline irrigation control group, had statistically significant reduction in mean total RSDI scores through Day 30 (p<0.0001). For the SNOT 22, the changes were -1.9 and -1.7, respectively (p<0.0001). All changes from baseline in RSDI, SNOT 22 and CATS scores were statistically significant compared to baseline and the saline irrigation control group.

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