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

Mometasone furoate is a synthetic corticosteroid. The chemical name is 1β,21-dichloro-11β,17α,20α-trihydroxy-16α,21-dihydroxy-16α-methylpregna-

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 1β,21-dichloro-11β,17α,20α-trihydroxy-16α,21-dihydroxy-16α-methylpregna-

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

The PROPEL® mini implant is comprised of a synthetic bioabsorbable co-polymer, poly(DL-lactide-co-glycolide) (PLG) and polyethylene glycol (active ingredient) which provide for gradual release of the drug.

**CONTRAINDICATIONS:**

- Patients with a known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS:**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND INTENDED USE**

The PROPEL® mini sinus implant is intended for use in patients 18 years of age following ethmoidal/frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening.

**PRECAUTIONS**

- Special care should be taken to avoid bleeding, handing or damaging the implant.
- The implant is not designed to be modified by the physician.

**STORAGE**

- The PROPEL® mini implant should be stored in a cool, dry place.
- The PROPEL® mini implant should be stored in a cool, dry place.

**PRIOR TO INSERTION**

- The implant should not be activated prior to insertion.
- The implant should not be activated prior to insertion.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**INDICATIONS AND CONTRAINDICATIONS**

- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.

**WARNINGS**

- The PROPEL® mini sinus implant is contraindicated in the following patients:
- Patients with known hypersensitivity to lactide, glycolide or caprolactone copolymers.
The ADVANCE II study was a prospective randomized, double-blind, concurrently controlled study that enrolled 105 patients with refractory chronic rhinosinusitis (CRS) at 33 study centers. This study utilized an intra-patient control design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the focal obstructive site (FSO). Adverse events (regardless of relationship to implant) reported in this clinical study. Adverse events (regardless of relationship to implant) reported in the non-drug control version of the implant. The primary safety endpoint was cosmetic sinus surgery defined as an objectively clinically significant sustained elevation (≥ 110 mm Hg) in intra-observer pressure through Day 90. Other examinations also included assessment of changes in CRSSNQoL development of late sequelae. The secondary safety endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 90 (p=0.96). There were no clinically significant increases in intra-observer pressure and no clinically significant changes from baseline in less operations.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients with each unilateral or bilateral recurrent chronic polyposic sinus disease at 7 study sites. The study centers. Follow-up assessments included endoscopic examination and scoring through 2 months, with patient symptom scoring through the CRSSNQoL (15 sites) and the University of Arkansas feasibility trial (3 sites). Lower scores indicate improvement. The CONSENSUS II pilot study was not designed to allow statistical comparisons. The study utilized an investigator-controlled design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO, and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoidal edema in the FSO. In the CONSENSUS II pilot study, 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version.

The ADVANCE study was a single-cohort, open-label trial that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 clinical study centers. A total of 45 patients received the 23 mm PROPEL sinus implant and 5 patients received a shorter version. The study utilized an investigator-controlled design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting version of the implant. Thirty-eight patients were enrolled in the 23 mm implant group and 22 patients in the short implant group. The other category of post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO. This pair correlation coefficient was 0.958, which is suggestive of a positive correlation between the two parameters.

The ADVANCE II study was a single-cohort, open-label that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 study centers. The scores indicate improvement. The ADVANCE II study was not designed to allow statistical comparisons. The primary safety endpoint was cosmetic sinus surgery defined as an objectively clinically significant sustained elevation (≥ 110 mm Hg) in intra-observer pressure through Day 90. Other examinations also included assessment of changes in CRSSNQoL development of late sequelae. The secondary safety endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 90 (p=0.96). There were no clinically significant increases in intra-observer pressure and no clinically significant changes from baseline in less operations.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients with each unilateral or bilateral recurrent chronic polyposic sinus disease at 7 study sites. The study utilized an investigator-controlled design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO, and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoidal edema in the FSO. In the CONSENSUS II pilot study, 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version.

The ADVANCE study was a single-cohort, open-label trial that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 clinical study centers. A total of 45 patients received the 23 mm PROPEL sinus implant and 5 patients received a shorter version. The study utilized an investigator-controlled design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting version of the implant. Thirty-eight patients were enrolled in the 23 mm implant group and 22 patients in the short implant group. The other category of post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO. This pair correlation coefficient was 0.958, which is suggestive of a positive correlation between the two parameters.

The ADVANCE II study was a single-cohort, open-label that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 study centers. The scores indicate improvement. The ADVANCE II study was not designed to allow statistical comparisons. The primary safety endpoint was cosmetic sinus surgery defined as an objectively clinically significant sustained elevation (≥ 110 mm Hg) in intra-observer pressure through Day 90. Other examinations also included assessment of changes in CRSSNQoL development of late sequelae. The secondary safety endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 90 (p=0.96). There were no clinically significant increases in intra-observer pressure and no clinically significant changes from baseline in less operations.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients with each unilateral or bilateral recurrent chronic polyposic sinus disease at 7 study sites. The study utilized an investigator-controlled design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO, and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoidal edema in the FSO. In the CONSENSUS II pilot study, 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version.

The ADVANCE study was a single-cohort, open-label trial that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 clinical study centers. A total of 45 patients received the 23 mm PROPEL sinus implant and 5 patients received a shorter version. The study utilized an investigator-controlled design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting version of the implant. Thirty-eight patients were enrolled in the 23 mm implant group and 22 patients in the short implant group. The other category of post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO. This pair correlation coefficient was 0.958, which is suggestive of a positive correlation between the two parameters.

The ADVANCE II study was a single-cohort, open-label that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 study centers. The scores indicate improvement. The ADVANCE II study was not designed to allow statistical comparisons. The primary safety endpoint was cosmetic sinus surgery defined as an objectively clinically significant sustained elevation (≥ 110 mm Hg) in intra-observer pressure through Day 90. Other examinations also included assessment of changes in CRSSNQoL development of late sequelae. The secondary safety endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 90 (p=0.96). There were no clinically significant increases in intra-observer pressure and no clinically significant changes from baseline in less operations.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients with each unilateral or bilateral recurrent chronic polyposic sinus disease at 7 study sites. The study utilized an investigator-controlled design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO, and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoidal edema in the FSO. In the CONSENSUS II pilot study, 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version.

The ADVANCE study was a single-cohort, open-label trial that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 clinical study centers. A total of 45 patients received the 23 mm PROPEL sinus implant and 5 patients received a shorter version. The study utilized an investigator-controlled design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting version of the implant. Thirty-eight patients were enrolled in the 23 mm implant group and 22 patients in the short implant group. The other category of post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO. This pair correlation coefficient was 0.958, which is suggestive of a positive correlation between the two parameters.

The ADVANCE II study was a single-cohort, open-label that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 study centers. The scores indicate improvement. The ADVANCE II study was not designed to allow statistical comparisons. The primary safety endpoint was cosmetic sinus surgery defined as an objectively clinically significant sustained elevation (≥ 110 mm Hg) in intra-observer pressure through Day 90. Other examinations also included assessment of changes in CRSSNQoL development of late sequelae. The secondary safety endpoint was not demonstrating a statistically significant reduction in the need for post-operative interventions at Day 90 (p=0.96). There were no clinically significant increases in intra-observer pressure and no clinically significant changes from baseline in less operations.

The CONSENSUS II pilot study was a randomized, double-blind, concurrently controlled feasibility trial that enrolled 50 patients with each unilateral or bilateral recurrent chronic polyposic sinus disease at 7 study sites. The study utilized an investigator-controlled design to assess the safety and efficacy of the PROPEL sinus implant compared to the non-drug control version of the implant. The primary efficacy endpoint was the reduction in need for post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO, and/or oral steroid intervention warranted to resolve recurrent inflammation or polypoidal edema in the FSO. In the CONSENSUS II pilot study, 43 patients received the 23 mm PROPEL sinus implant and 7 patients received a shorter version.

The ADVANCE study was a single-cohort, open-label trial that enrolled 50 patients with either unilateral or bilateral recurrent sinus disease at 7 clinical study centers. A total of 45 patients received the 23 mm PROPEL sinus implant and 5 patients received a shorter version. The study utilized an investigator-controlled design to assess the safety and efficacy of the drug-eluting PROPEL sinus implant compared to the non-drug eluting version of the implant. Thirty-eight patients were enrolled in the 23 mm implant group and 22 patients in the short implant group. The other category of post-operative surgical intervention required to debride obstructive adhesions or the need for surgical intervention or additional oral steroid intervention required to resolve recurrent inflammation or polypoidal edema in the FSO. This pair correlation coefficient was 0.958, which is suggestive of a positive correlation between the two parameters.