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Drug-Eluting Sinus Implants

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
SUR706.017: Absorbable Nasal Implant for Treatment of Nasal Valve Collapse

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current generally accepted standards of and developed by nonprofit professional association(s) for the relevant clinical specialty, third-party entities that develop treatment criteria, or other federal or state governmental agencies. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and generally accepted standards of medical care. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Drug-Eluting Sinus Implants

Placement of a mometasone furoate sinus implant (Propel®, Propel mini, or Propel contour sinus implant), consistent with the U.S. Food and Drug Administration (FDA) device-approved indications for that specific product (See **NOTE 1**) **may be considered medically necessary** in conjunction with an appropriately indicated sinus surgery for that product when the following criteria are met:

- Individual ≥18 years of age; AND
- Individual has no contraindications to the use of mometasone furoate.

Placement of a mometasone furoate sinus implant (Sinuva), consistent with the FDA drug-approved label, **may be considered medically necessary** for the treatment of chronic rhinosinusitis with nasal polyps in patients who have had ethmoid sinus surgery and meet ALL of the following criteria:

- Individual ≥ 18 years of age; AND
- Individual has no contraindications to the use of mometasone furoate.

Placement of a mometasone furoate sinus implant **is considered experimental, investigational and/or unproven** for all other non-Food and Drug Administration approved uses.

NOTE 1: See the Policy Guidelines section for indications for the following devices:

- PROPEL Sinus Implant,
- PROPEL Mini Sinus Implant, and
- PROPEL Contour Sinus Implant.

Policy Guidelines

PROPEL™ Sinus Implant (2)
This device is indicated for use in patients ≥ 18 years of age following ethmoid sinus surgery to maintain patency, thereby reducing the need for post-operative interventions such as surgical adhesion lysis and/or use of oral steroids.

PROPEL® Mini Sinus Implant (4)
This device is indicated for use in patients ≥ 18 years of age following ethmoid/frontal sinus surgery to maintain patency of the ethmoid sinus or frontal sinus opening.

PROPEL® Contour Sinus Implant (6)
This device is indicated for use in patients ≥ 18 years of age to maintain patency of the frontal and maxillary sinus ostia following sinus surgery and locally deliver steroids to the sinus mucosa.

Description

Steroid-eluting sinus stents are devices used postoperatively following endoscopic sinus surgery (ESS) or for treatment of recurrent sinonasal polyposis following ESS. These devices maintain patency of the sinus openings in the postoperative period, and/or serve as a local drug delivery vehicle. Reducing postoperative inflammation and maintaining patency of the sinuses may be important in achieving optimal sinus drainage and may impact recovery from surgery and/or reduce the need for additional surgery.

Chronic Rhinosinusitis
Chronic rhinosinusitis is an inflammatory sinus condition that has a prevalence between 1% and 5% in the U.S. population. (8)

Treatment

Endoscopic sinus surgery (ESS) is typically performed on patients with chronic rhinosinusitis unresponsive to conservative treatment. The surgery is associated with high rates of improvement in up to 90% of more appropriately selected patients. However, there are no high-quality randomized controlled trials (RCTs) comparing functional ESS with continued medical management or alternative treatment approaches. Because of the high success rates and minimally invasive approach, these procedures have rapidly increased in frequency, with an estimated 250,000 procedures performed annually in the United States. (9) They can be done either in the physician's office under local anesthesia or in the hospital setting under general anesthesia.

Endoscopic sinus surgery involves the removal of small pieces of bone, polyps, and débridement of tissue within sinus cavities. There are a number of variations on the specific approach, depending on the disorders being treated and the preferences of the treating surgeon. For all procedures, there is substantial postoperative inflammation and swelling, and postoperative care is, therefore, a crucial component of endoscopic sinus surgery.

There are a number of postoperative treatment regimens, and the optimal regimen is uncertain. Options include saline irrigation, nasal packs, topical steroids, systemic steroids, topical decongestants, oral antibiotics, and/or sinus cavity débridement. Several randomized controlled trials (RCTs) have evaluated treatment options, but not all strategies have been rigorously evaluated. (10-13) A 2011 systematic review has evaluated the evidence for these therapies. (9) Reviewers concluded that the evidence was not strong for any of these treatments but that some clinical trial evidence supported improvements in outcomes. The strongest evidence supported use of nasal saline irrigation, topical nasal steroid spray, and sinus cavity débridement.

Some form of sinus packing is generally performed postoperatively. Simple dressings moistened with saline can be inserted manually following surgery. Foam dressings are polysaccharide substances that form a gel when hydrated and can be used as nasal packs for a variety of indications. (14) Middle meatal spacers are splint-like devices that prop open the sinus cavities post-endoscopic sinus surgery but are not designed for drug delivery. There is some RCT evidence that middle meatal spacers may reduce the formation of synechiae following endoscopic sinus surgery, although the available studies have significant heterogeneity in this outcome. (15)

Sinus Stents and Implants

Implantable sinus stents and implants are another option for postoperative management following endoscopic sinus surgery. These implants are intended to stabilize the sinus openings and the turbinates, reduce edema, and/or prevent obstruction by adhesions. They can also be infused with medication that can be delivered topically over an extended period of time, and this local delivery of medications may be superior to topical application in the postoperative setting.

Regulatory Status

Sinus Implant Under FDA Device Approvals

In 2011, the PROPEL® system (Intersect ENT, Menlo Park, CA) was approved by the FDA through the premarket approval process (P100044). This device is a self-expanding, bioabsorbable, steroid-eluting stent intended for use in the ethmoid sinus. It is placed via endoscopic guidance using a plunger included with the device. Steroids (mometasone furoate) are released over an approximate duration of 30 days. The device dissolves over several weeks and therefore does not require removal. In 2012, a smaller version of the PROPEL device, the PROPEL Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus. FDA product code: OWO.

Sinus Implant under FDA Drug Approvals

SINUVA™ Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) was initially approved in 1987. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The corticosteroid is released over 90 days and the bioabsorbable polymers soften over this time. The implant is removed at day 90 or earlier using standard surgical instruments. The SINUVA™ Sinus Implant is indicated for the treatment of nasal polyps in adult patients ≥ 18 years of age who have had ethmoid sinus surgery. In 2023, the indications for Sinuva were revised to include the treatment of chronic rhinosinusitis with nasal polyps in adult patients ≥18 years of age who have had ethmoid sinus surgery. (1)

Rationale

This policy is based on the U.S. Food and Drug Administration (FDA) drug labeled indications for Sinuva, and the device labeled indications for Propel, Propel mini and Propel Contour.

DRUG APPROVAL

Sinuva® (1)

Clinical Studies

The Sinuva Sinus Implant was evaluated in 450 patients, 18 years of age and older, with chronic rhinosinusitis with nasal polyps and a history of ethmoid sinus surgery. The development program included a trial of 6 months duration (Study 1: NCT01732536), another trial of 90 days duration (Study 2: NCT02291549), and a repeat placement study of 1-year duration (Study 3: NCT03358329). The efficacy of SINUVA Sinus Implant is based primarily on Study 2 as described below.

Study 2 was a randomized, controlled, single-blind, multicenter (all sites were in the U.S.) study with 300 patients: 201 patients were assigned to the treatment group and underwent bilateral placement of the Sinuva Sinus Implants in the ethmoid sinuses. The remaining 99 patients were assigned to the control group and underwent a placebo (sham) procedure, consisting of

advancement of the Delivery System with the Sinuva Sinus Implant into the ethmoid sinuses, followed by removal of the Delivery System without deployment of the SINUVA Sinus Implant. The Implants were removed by Day 60 to allow blinded grading at Day 90. All patients [treatment (T) and control (C) groups] were required to use a mometasone furoate nasal spray once daily (200 mcg of mometasone furoate) through Day 90.

The co-primary efficacy endpoints were:

- Change from baseline to Day 30 in Nasal Obstruction/Congestion score, as determined by patients using a daily diary; and
- Change from baseline to Day 90 in bilateral polyp grade, as determined from video-endoscopies reviewed by an independent panel of 3 sinus surgeons who were masked to treatment assignment.

The study population consisted of adult patients (≥ 18 years of age) diagnosed with chronic rhinosinusitis who had undergone prior bilateral total ethmoidectomy but were indicated for revision endoscopic sinus surgery because they presented with recurrent nasal obstruction/congestion symptoms and recurrent bilateral sinus obstruction due to nasal polyps. Subjects were excluded for other grade 3 or 4 adhesions/synechiae, grade 4 polyps, acute bacterial or invasive fungal sinusitis, and immune deficiency, including cystic fibrosis. There were no statistically significant differences between groups in baseline demographics and clinical characteristics, except the treatment group had a higher proportion of asthma patients (T: 74% vs. C: 62%) and higher mean Percent Ethmoid Sinus Obstruction score [T: 76 (SD 17.4) vs. C: 69 (SD 19.9)]. The random imbalances did not impact treatment effect.

The co-primary efficacy results are presented in Table 1. The treatment group demonstrated a statistically significant difference from baseline to Day 30 in Nasal Obstruction/Congestion score and from baseline to Day 90 in bilateral polyp grade, compared to the control group.

Table 1: Co-Primary Efficacy Results with the SINUVA Sinus Implant (Study 2)

	Treatment (N = 201)	**Control (N = 99)**
Nasal Obstruction/Congestion Score[a]		
N	201	99
Baseline, Mean (SD)	2.36 (0.49)	2.35 (0.48)
Change from Baseline, Mean (SD)	-0.80 (0.73)	-0.56 (0.62)
Difference vs. Control (95% CI)[b]	-0.23 (-0.39, -0.06)	
Bilateral Polyp Grade[c]		
N	195	97
Baseline, Mean (SD)	5.48 (1.13)	5.43 (1.01)
Change from Baseline, Mean (SD	-0.56 (1.06)	-0.15 (0.91)
Difference vs. Control (95% CI)[b]	-0.35 (-0.60, -0.09)	

CI: Confidence Interval.

a) from baseline in Nasal Obstruction/Congestion was assessed on a scale of 0–3 where 0=No symptoms, 1=Mild symptoms, 2=Moderate symptoms, and 3=Severe symptoms. Scores were assessed using a daily diary for 7 days immediately preceding the baseline and Day 30 visits.
b) Based on analysis of covariance (ANCOVA) model with baseline value as a covariate and site and treatment group as fixed effects.
c) Change from baseline to Day 90 in bilateral polyp grade was assessed based on grading of video-endoscopies by an independent panel of 3 sinus surgeons who were blinded to treatment assignment. Polyps were graded as follows: 0=No visible polyps, 1=Small amount of polyps confined in middle meatus, 1.5=1+ polypoid edema obstructing ≥ 25% of the ethmoid sinus cavity, 2=Expanded amount of polyps confined in middle meatus, 2.5=2 + polypoid edema obstructing ≥ 50% of the ethmoid sinus cavity, 3=Polyps extending beyond middle meatus, but not totally obstructing the nasal cavity, 3.5=3 + polypoid edema obstructing ≥ 75% of the ethmoid sinus cavity, 4=Polyps completely obstructing the nasal cavity.

Change from baseline to Day 90 in the mean Percent Ethmoid Sinus Obstruction score (100 mm VAS), as judged by the independent panel [Difference vs. control: -7.96%; 95% CI (-12.1, -3.8)], met statistical significance and supported the co-primary endpoints.

DEVICE APPROVALS

Propel™(3)

The principal safety and effectiveness evidence for the Propel™ comes from the pivotal clinical study, ADVANCE II and is supported by the ADVANCE and CONSENSUS II clinical studies. These studies evaluated the safety, effectiveness and performance of the Propel™ when used in patients with chronic sinusitis following Functional Endoscopic Sinus Surgery (FESS). Subjects in all studies provided written informed consent. Major study characteristics are summarized in Table 2.

Table 2: Major Characteristics of the Clinical Studies

Clinical Study	Study Design	Objective	Number of Sites	Number of Subjects
ADVANCE II (pivotal)	Prospective, randomized, double-blind, concurrently controlled, multi-center Intra-patient control	Assess the safety and effectiveness of the Propel™ Sinus Implant when used following Functional Endoscopic Sinus Surgery (FESS) in patients with chronic sinusitis. Characterize Ocular Safety	11	105
ADVANCE	Prospective, single arm, multi-center	Generate additional performance, and safety data, for the Propel™ Sinus Implant when used following FESS in patients with chronic sinusitis. Characterize Ocular Safety	7	50

Consensus II (pilot)	Prospective, randomized, double-blind, concurrently controlled, multi-center Intra-patient control	Assess the safety, effectiveness, and performance of the Propel™ Sinus Implant when used following Functional Endoscopic Sinus Surgery (FESS) in patients with chronic rhinosinusitis	4	50

Advance II

Study Design

The ADVANCE II clinical study was a prospective, randomized, double-blind, concurrently controlled, multi-center study that enrolled 105 subjects at 11 U.S. sites. The objective of the study was to assess the safety and effectiveness of the Propel™ when used following Functional Endoscopic Sinus Surgery (FESS) in patients with chronic sinusitis (CS). The study utilized an intra-patient control design to assess the safety and effectiveness of the Propel™ compared to a non-drug-eluting control that is identical in appearance. Patients returned for periodic follow-up exams over a total of 90 days.

The non-drug-eluting implant was selected as the control to ensure blinding of both physician and patient to sinus treatment assignment. The drug-eluting and control versions are identical in appearance, as is the delivery system and packaging.

Use of an intra-patient control was selected as this study design minimizes variability that would be inherent in a parallel patient group design -most notably, variability introduced by concomitant medication usage. To eliminate any potential for bias introduced from the treating physician, a panel of 3 blinded sinus surgeons independently graded the 30-day endoscopic videos. The videos were blinded to treatment effect and randomized (not provided in pairs).

The primary effectiveness endpoint of reduction in post-operative interventions was selected to provide evidence of a clinically meaningful patient benefit to clearly demonstrate the contribution of the addition of mometasone furoate to the implant.

Success/failure criteria:

The Primary Safety Endpoint was Ocular Safety defined as absence of clinically significant sustained elevation (≥10 mm Hg) in intraocular pressure through Day 90. Ocular examinations also included assessment of changes in or development of lens opacities.

The Primary Efficacy Endpoint was the reduction in need for Post-Operative Interventions at Day 30, as determined from video-endoscopies reviewed by a panel of three independent blinded sinus surgeons. Post-Operative Intervention was a composite endpoint that included:

- Surgical Intervention required to separate an adhesion and/or
- Oral Steroid Intervention warranted to resolve recurrent ethmoid sinus inflammation, edema and/or polyp recurrence.

Pre-Specified Statistical Analysis Plan: The primary effectiveness hypothesis was that the Propel™ would reduce the need for Post-Operative Interventions at Day 30 compared to the control.

The Primary Safety Hypothesis was that the Propel™ is safe, as evidenced by the proportion of patients experiencing a clinically significant elevation in IOP being demonstrably less than 10%.

Follow-up Schedule
Baseline evaluations included a routine history and physical exam, ENT-HNS evaluation and CT scan to confirm CS diagnosis and candidacy for sinus surgery, and an ocular examination (IOP measurement, cataracts grading). Follow-up assessments occurred prior to hospital discharge or clinic release and at post-operative days 14, 30, 60 and 90 post procedure. Ocular examinations included intraocular pressure (IOP) measurements at all visits. The baseline and day 90 ocular exams included dilated slit-lamp examination for cataracts, visual acuity and estimation of vertical cup/disc ratio.

Clinical Endpoints:
The Primary Effectiveness Endpoint was the reduction in need for Post-Operative Interventions at Day 30, as determined from video-endoscopies reviewed by a panel of three independent blinded sinus surgeons. Post-Operative Intervention was a composite endpoint that included:

- Surgical Intervention required to separate an adhesion and/or
- Oral Steroid Intervention warranted to resolve recurrent ethmoid sinus inflammation, edema and/or polyp recurrence.

The Primary Safety Endpoint was Ocular Safety defined as absence of clinically significant elevation in intraocular pressure through Day 90.

Accountability of PMA Cohort
A total of 105 patients were enrolled in the study. One hundred two (102) of the 105 patients completed the ENT follow-up visits through 90 days, representing a follow-up rate of 97.1%. One hundred three (103) of the 105 patients completed the ocular follow-up visits through 90 days, representing a follow-up rate of 98.0%. No patient required termination from the study due to an adverse event.

Study Population Demographics and Baseline Parameters
The study population consisted of 57.1% males and the mean age was 46.5 years. The five most frequently reported symptoms reported by patients prior to the sinus surgery were, in order: nasal obstruction/congestion (90.5%), headache (64.8%), facial pain/pressure (61.0%), discolored nasal drainage (54.3%) and hyposmia/anosmia (50.5%). These findings are consistent with the typical set of persisting symptoms reported by chronic sinusitis patients. Thirty-one study patients (29.5%) had undergone one or more prior sinus procedures and this was predominantly FESS and septoplasty (77.4% and 48.4%, respectively). The mean total Lund-Mackay CT stage was 12.8. Right and left sides were well balanced with respect to mean CT stage (6.5 right vs. 6.4 left). Fifty-nine percent of study patients presented with polyps at

baseline. All patients underwent bilateral ethmoidectomy at the time of sinus surgery for this study.

Safety Results
The primary safety endpoint was met. There were no clinically significant elevations in intraocular pressure through Day 90. There were no clinically significant changes in lens opacities observed in the clinical study.

Adverse events observed: Recurrent sinusitis was the most frequently reported adverse event type, reported in 34 of the 105 patients (32.4%). Sinusitis was the only event type localized by sinus side; this was possible in 14 of the events. Six occurred on treatment sides and 8 occurred on the control sides. Two of the adverse events (sinusitis) were determined to be related to the study device. Both resolved without sequelae. There were no serious adverse events reported in the study.

Effectiveness Results
The primary effectiveness endpoint was met. The rate of Post-Operative Intervention was 46.9% on the control sides compared to 33.3% on the treatment sides. This difference was statistically significant (p=0.0280) and represents a 29% relative reduction in Post-Operative Interventions.

<u>ADVANCE Study</u>
The ADVANCE study was a prospective, single-arm, multi-center, open label trial which enrolled 50 patients at 7 sites in the United States. As a consecutive case series, the study provided additional evidence of the clinical utility of the Propel™ in standard clinical practice through the Day 60 time point. The study generated additional performance and safety data, including characterization of ocular safety, for the Propel™ implant. A 6 month time point provided data on the longer-term impact of sinus surgery itself on patient symptoms and outcomes. The study enrolled a single cohort with either unilateral or bilateral ethmoid sinus disease who met eligibility criteria.

Success/Failure Criteria
The study was considered successful if Device Success, defined as successful access and deployment of a Propel™ to the target site, was accomplished in 90% of deployments.

The study was considered a success if the frequency of Serious Adverse Local Tissue (SALT) response through 30 days post-procedure was < 15%.

The ADVANCE study utilized similar inclusion and exclusion criteria as the pivotal study, ADVANCE II, but allowed unilateral ethmoidectomy.

Follow-up Schedule
Baseline evaluations included a routine history and physical exam, ENT-HNS evaluation and CT scan to confirm CS diagnosis and candidacy for sinus surgery and an ocular examination (IOP

and cataracts). Follow-up assessments occurred prior to hospital discharge or clinic release and at Day 7, 14, 21, 30 and 60 post procedure. Follow-up examinations included endoscopic examination and scoring, patient symptom questionnaires, review of concomitant medications and review for adverse events. Patients underwent an end-of-treatment ocular examination at Day 30, consisting of IOP measurement and dilated slit-lamp examination for cataracts. At month 6, the last study visit, patients were asked to complete symptom questionnaires.

Sinus-related safety endpoints were assessed by direct endoscopic examination performed by the sinus surgeon at follow-up visits. Sinus-related adverse events were determined by a combination of objective endoscopic observation and patient symptoms. The SALT endpoint (primary safety endpoint) was determined by endoscopic examination and per the definition, required removal of the implant(s) to resolve.

Ocular safety assessment included baseline and end-of-treatment (Day 30) measurement of IOP and dilated slit-lamp examination of lens opacities (cataracts).

Patients' symptoms were assessed over time using accepted disease-specific scoring instruments. The Rhinosinusitis Disability Index (RSDI), the Sinonasal Outcomes Tests 22 (SNOT-22) and Total Nasal Symptom Scoring (TNSS).

Clinical Endpoints
The Primary Performance Objective was Device Success, defined as the ability to successfully deliver and deploy the sinus implant to the target site.

The Primary Safety Objective was the rate of Serious Adverse Local Tissue (SALT) response through 30 days post-procedure.

Accountability of Subjects
A total of 50 subjects were enrolled at seven investigational centers. Forty-nine of the 50 subjects completed the study through 60 days, representing a follow-up rate of 98%. Forty-five subjects (90%) completed follow-up through 6 months. Of the 50 patients enrolled, 10 had unilateral implant placement, and 40 had bilateral implant placement, resulting in a total of 90 treated sinuses. One of the patients with bilateral implant placement had an artificial eye, resulting in a total of 89 eyes for evaluation of ocular safety. One subject withdrew from the study after Day 30 due to scheduling difficulties.

Study Population Demographics and Baseline Parameters
In the overall study population, the proportion of male subjects was 52.0% and the mean age was 44.2 years. The most frequently reported symptoms reported by subjects prior to the sinus surgery were, in order: nasal obstruction/congestion (94.0%), headache (82.0%), fatigue (74.0%) and facial pain/pressure (68.0%). These findings are consistent with the typical set of persisting symptoms reported by chronic sinusitis patients. Mean baseline Lund-Mackay CT stage was 11.2, 28% had undergone a prior sinus procedure and 66% presented with nasal/sinus polyps.

Safety and Effectiveness Results
The primary performance endpoint (device success > 90%) was met. The device success rate was 100%.

The Propel™ implant was substantially reabsorbed from the sinus cavity within 4 to 6 weeks during routine follow-up patient care after sinus surgery.

Safety Results
The primary safety endpoint was met. The analysis of safety was based on the rate of SALT measured for each sinus implanted with the Propel™ at the 30-day time point. SALT was observed in six sinuses (3 patients) during the study, giving a rate of 6.7% through 30 Days. Thus, the primary safety endpoint (observed SALT rate <15% through Day 30) was achieved. There was no SALT observed after 30 days. There were no clinically significant changes from baseline in IOP or lens opacities.

Adverse Events
A total of 54 adverse events occurred in 32 of the 50 patients through 60 days. There was one device-related adverse event reported (headache and nasal burning) that resolved without sequelae.

Effectiveness Results
Mean scores for ethmoid sinus inflammation were similar to the treatment arm of CONSENSUS II and were minimal at all time points. The observed rate of polypoid tissue formation of any grade at 30 days was 10.0%; adhesions 1.1%; and middle turbinate lateralization 4.4%.

Patient reported outcomes were included in the ADVANCE study to assess the impact of sinus surgery itself on patient symptoms. The mean changes from baseline to Day 60 and 6 months in total RSDI score were -36.2 and -29.7, respectively ($p<0.0001$). 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 TNSS were statistically significant ($p<0.0002$).

<u>CONSENSUS II Study</u>
The CONSENSUS II study was the first clinical trial to evaluate the safety and effectiveness of the Propel™. CONSENSUS II was a randomized, double-blind, multicenter clinical study in which 50 patients were enrolled at 4 clinical sites in the United States and included follow-up through 60 days. The objective of the study was to assess the safety, effectiveness, and performance of the Propel™ when used following Functional Endoscopic Sinus Surgery (FESS) in patients with chronic rhinosinusitis. Patients were enrolled in two groups. One group (Cohort A) used an intra-patient control design to assess performance of the Propel™ compared to the control (non-drug-eluting implant). The other group of patients (Cohort B) received bilateral Propel™ implants and served as a pharmacokinetics (PK) study group. A Continuation Cohort was added to expand the size of the clinical trial. All patients in the Continuation Cohort used an intra-patient control. Patients were enrolled chronologically into the following three study cohorts:

Cohort A (Pilot Phase; Randomized; Double-Blind; Intra-Patient Control): 20 patients received the Propel™ in one ethmoid sinus and a control in the opposite ethmoid sinus. The side receiving the Propel™ was randomized. This cohort served as an intra-patient control in order to assess the performance and ability of the Propel™ to minimize post-surgical inflammation. Drug-eluting implants were placed unilaterally and compared to the control (non-drug-eluting implant) over time. The first 7 patients enrolled received a shorter length version of the Propel™. The study device was then changed to the current 23mm version. The remaining 13 patients received the 23 mm version of the Propel™.

Cohort B (Non-Randomized): Five patients received the Propel™ (23 mm version) bilaterally (in both ethmoid sinuses) for a total of 2 drug-eluting implants per patient. This patient cohort was included to evaluate whether any systemic exposure was detectable when 2 drug-eluting implants were used. Patients from Cohort B were included in a pharmacokinetic evaluation, requiring serial blood sampling to assess plasma mometasone furoate and cortisol concentrations. Intraocular pressure was also measured at baseline and end of treatment (Day 30) in these subjects.

Continuation Cohort (Randomized; Double-Blind; Intra-Patient Control): At completion of enrollment of the initial 25 patients in Cohort A and Cohort B, an additional 25 patients were enrolled into the randomized Cohort A group. All patients received the 23mm length Propel™.

Success/Failure Criteria
The three primary objectives (performance, safety, effectiveness) needed to be satisfied in order for the study to be considered successful. The study was considered a success if: 1) the device placement success rate was at least 75%, 2) ethmoid sinus inflammation at Day 21 was reduced (by at least half a standard deviation) in the treatment arm when compared to the control and 3) the rate of Serious Adverse Local Tissue response through 30 days post-procedure was less than 20%.

Clinical Inclusion and Exclusion Criteria
The inclusion and exclusion criteria of the CONSENSUS II study were similar to those used in the pivotal study, ADVANCE II.

Follow-up Schedule
Baseline evaluations included a routine history and physical exam, ENT-HNS evaluation and CT scan to confirm CRS diagnosis and candidacy for sinus surgery. Follow-up assessments occurred prior to hospital discharge or clinic release and at Day 7, 14, 21, 30, 45 and 60 post procedure. Follow-up examinations included endoscopic examination and scoring, review of concomitant medications and review for adverse events. Patients in Cohort B underwent weekly blood draws through Day 30 and an IOP measurement at baseline and Day 30.

Clinical Endpoints

The Primary Performance Objective was Device Success, defined as the ability to successfully deliver and deploy the implant to the target site.

The Primary Effectiveness Objective was a reduction in ethmoid sinus inflammation at Day 21, as measured by the physician's score using a 100 mm Visual Analog Scale (VAS) during endoscopic examination.

The Primary Safety Objective was the rate of Serious Adverse Local Tissue response (SALT) through 30 days post-procedure.

Accountability of Subjects
A total of 50 patients were enrolled in the study at four investigational centers. Forty-nine (49) of the 50 subjects completed all follow-up visits through 60 days, representing a follow-up rate of 98%.

Study Population Demographics and Baseline Parameters
In the overall study population, the proportion of male subjects was 56.0% and the mean age was 47.1 years. The most frequently reported symptoms reported by subjects prior to the sinus surgery were, in order: nasal obstruction/congestion (80.0%), facial pain/pressure (40.0%), headache (34.0%), and anosmia (30.0%). These findings are consistent with the typical set of persisting symptoms reported by chronic rhinosinusitis patients. Mean baseline Lund-Mackay CT stage was 13.6, 42% had undergone a prior sinus procedure and 76% presented with nasal/sinus polyps.

Safety and Effectiveness Results
The primary performance endpoint (device success > 75%) was met. The device success rate was 100% in the overall study population, and therefore, in each study cohort as well.

The device was substantially reabsorbed from the sinus cavity within 4 to 6 weeks as seen during routine follow-up patient care after sinus surgery.

Safety Results
The primary safety endpoint was met: SALT was not observed in any sinus during the study. The analysis of safety was based on the rate of SALT measured for each sinus implanted with the Propel™ through the 30-day time point. There was no instance where the implant (either treatment or control) required removal due to SALT.

Systemic Safety: Plasma MF concentrations were not quantifiable at any time point. The mean cortisol concentration at baseline was within normal limits at 6.16 µg/dL. Mean cortisol concentrations at follow-up time points were also within normal limits and indicate no evidence of adrenal suppression.

Ocular Safety: There were no clinically significant changes in intraocular pressure (IOP) observed.

Adverse Events
There were no device-related adverse events. A total of 47 adverse events occurred in 25 of the 50 patients.

Effectiveness Results
The primary effectiveness endpoint was met. For Combined Cohort A (all 23 mm implants; n=38), mean differences in ethmoid sinus inflammation between sides was 12.0 mm (p=0.0032) at day 21. A reduction in inflammation from Days 14 to 60 was demonstrated in favor of the Propel™, with statistically significant reductions also observed at days 30 and 45 (p≤0.0022). The drug-eluting implant reduced the frequency of middle turbinate lateralization, significant adhesion occurrence, and polypoid tissue formation through day 30, compared to the control implant.

Summary of Overall Device Performance
In all three studies, implant placement occurred following ethmoidectomy. 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 sub-optimal apposition, crossed struts or inadvertent removal, and 3 (0.8%) were damaged during preparation. In these 3 cases, a new implant was used successfully.

Outside US Clinical Experience:
The Propel™ was used in 18 patients in Canada under the Special Access program. There were no reported adverse events.

Propel® Mini Sinus Implant (5)
The applicant performed a clinical study (PROGRESS) to establish a reasonable assurance of safety and effectiveness of the use of the PROPEL Mini sinus implant (approved in P100044/S001) following Functional Endoscopic Sinus Surgery (FESS) to maintain patency of the frontal sinus opening in patients with chronic sinusitis in the U.S. Data from this clinical study were the basis for the PMA (premarket approval application) approval decision. A summary of the clinical study is presented in the following subsections.

Three other studies were previously conducted to assess the safety and effectiveness of the PROPEL sinus implant (approved in P100044) when used in the ethmoid sinus in patients with chronic sinusitis following FESS.

Table 3: Major Characteristics of the Clinical Studies

Clinical Study	Study Design	Objective	Number of Sites	Number of Subjects
ADVANCE II (pivotal)	Prospective, randomized, double-blind, concurrently	Assess the safety and effectiveness of the Propel™ Sinus Implant when used following Functional	11	105

	controlled, multi-center Intra-patient control	Endoscopic Sinus Surgery (FESS) in patients with chronic sinusitis. Characterize Ocular Safety		
ADVANCE	Prospective, single arm, multi-center	Generate additional performance, and safety data, for the Propel™ Sinus Implant when used following FESS in patients with chronic sinusitis. Characterize Ocular Safety	7	50
Consensus II (pilot)	Prospective, randomized, double-blind, concurrently controlled, multi-center Intra-patient control	Assess the safety, effectiveness, and performance of the Propel™ Sinus Implant when used following Functional Endoscopic Sinus Surgery (FESS) in patients with chronic rhinosinusitis	4	50
PROGRESS Mini Cohort (pivotal – frontal indication)	Prospective, randomized, double-blind, concurrently controlled, multi-center Intra-patient control	Assess the safety and effectiveness of the PROPEL Mini sinus implant in the frontal sinus opening when used following Functional Endoscopic Sinus Surgery in patients with chronic sinusitis.	11	80

<u>PROGRESS Clinical Study</u>

Study Design

Patients were treated between September 17, 2014 and September 9, 2015. The database for this (P100044/S018) reflected data collected through September 9, 2015 and included 80 patients. There were 11 investigational sites.

The PROGRESS clinical study (Mini Cohort) was a prospective, randomized, double-blind, concurrently controlled, multi-center study that enrolled 80 subjects at 11 U.S. sites. The objective of the study was to assess the safety and effectiveness of the PROPEL Mini sinus implant in the frontal sinus opening when used following endoscopic sinus surgery in patients with chronic sinusitis. The study utilized an intra-patient control design to assess the safety and effectiveness of the PROPEL Mini sinus implant compared to endoscopic sinus surgery alone. Patients returned for periodic follow-up exams over a total of 90 days. Results from the PROGRESS Mini Cohort study are presented here.

The rationale for selection of endoscopic sinus surgery alone as the choice of control was to compare the outcomes of stenting to the current standard of care. The patient underwent

bilateral endoscopic frontal sinus surgery following which only the treatment side received the PROPEL Mini sinus implant.

Use of an intra-patient control was selected as this study design minimizes variability that would be inherent in a parallel patient group design – most notably, variability introduced by concomitant medication usage. To eliminate the potential for bias in endoscopic grading, protocol required implants be removed at Day 21 and a blinded sinus surgeon independently graded the Day 30 endoscopic videos.

The primary efficacy endpoint of reduction in need for post-operative interventions was selected to provide evidence of a clinically meaningful patient benefit to clearly demonstrate the contribution of a mometasone furoate coated implant in the frontal sinus opening.

Success/failure Criteria
The primary efficacy endpoint was the reduction in need for Post-Operative Interventions at Day 30, as determined from video-endoscopies reviewed by an independent blinded sinus surgeon. Post-Operative intervention was a composite endpoint that included:

- Surgical Intervention required to debride obstructive adhesions or scar tissue formation in the frontal sinus opening and/or
- Oral Steroid Intervention warranted to resolve recurrent inflammation or polypoid edema in the frontal recess/ frontal sinus opening.

The implant safety was determined by the assessment of adverse events throughout the study.

Pre-Specified Statistical Analysis Plan
The primary effectiveness hypothesis was that the PROPEL Mini sinus implant would reduce the need for Post-Operative Interventions at Day 30 compared to the control.

Follow-up Schedule
Baseline evaluations included a routine history and physical exam, ENT-HNS evaluation and CT scan to confirm chronic rhinosinusitis diagnosis (if not performed within past 6 months) and candidacy for sinus surgery. Follow-up assessments occurred prior to hospital discharge or clinic release and at postoperative Days 7, 21, 30 and 90.

The follow-up assessments included endoscopic examinations and endoscopic video recording to DVD in addition to a CT scan conducted at the Day 90 visit only. At Day 21, the implant or its remnants were to be removed to allow for blinded review of video endoscopies at the Day 30 visit. Adverse events and serious adverse events were recorded and tabulated through day 30 and 90. Where possible and if applicable, adverse events were localized to a sinus location.

Clinical Endpoints

The primary efficacy endpoint was the reduction in need for Post-Operative Interventions at Day 30, as determined from video-endoscopies reviewed by a panel of three independent blinded sinus surgeons. Post-Operative Intervention was a composite endpoint that included:

- Surgical Intervention required to debride obstructive adhesions or scar tissue formation in the frontal sinus opening and/or
- Oral Steroid Intervention warranted to resolve recurrent inflammation or polypoid edema in the frontal recess/ frontal sinus opening.

The safety endpoint was assessment of adverse events and serious adverse events through Day 90.

Secondary efficacy endpoints at Day 30 as determined from video-endoscopies reviewed by the independent blinded sinus surgeon included: frequency and severity of adhesion/scarring formation in the FSO, degree of inflammation in the frontal recess/FSO using a 100 mm Visual Analog Scale (VAS) and frequency and grade of polypoid edema in the frontal recess/FSO. Additional secondary efficacy endpoints assessed by on-site investigators at all time points through 30 days included: frequency of post-operative interventions, endoscopic scores of inflammation using a 100 mm Visual Analog Scale (VAS), frequency and degree of adhesion/scarring formation in the FSO, frequency and grade of polypoid edema in the frontal recess/FSO and implant delivery success rate at device placement.

To be considered successful, the PROGRESS Study needed to pass the primary efficacy hypothesis. The hypothesis is that the drug-coated implant reduces the need for post-operative interventions at Day 30 compared to the control.

Accountability of PMA Cohort

A total of 80 patients were enrolled in the study. Seventy nine (79) of the 80 patients completed the ENT follow-up visits through Day 30, representing a follow-up rate of 98.8%. No patient required termination from the study due to an adverse event through Day 30. The efficacy analyses were based on the intent-to-treat (ITT) population, which consists of all randomized patients who underwent implant placement.

Study Population Demographics and Baseline Parameters

The study population consisted of 57.5% males and the mean age was 49.9 years. At baseline, 76.3% patients had polypoid edema (grade 2), in the frontal recess/frontal sinus opening; 37.5% patients had asthma; 7.5% patients had aspirin intolerance/allergy and 7.5% patients had Samter's Triad. The mean baseline total Lund-Mackay (L-M) score was 15.8; with 51.2% patients who had undergone at least one prior ESS. Control and treatment sides were well balanced with respect to mean L-M CT stage (8.0 control vs. 7.8 treatment side). All patients underwent bilateral traditional frontal sinusotomy prior to implant placement on one randomized side.

Safety Results

The analysis of safety was based on the intent-to-treat population in the Mini cohort of 80 patients available for the 90 day evaluation.

Adverse effects that occurred in the PMA clinical study: Sinusitis (acute and chronic) and headache were the most frequently reported AEs, in 21 (26.3%) patients and 9 (11.3%), respectively. Five adverse event types (headache, left upper eyelid swelling, epistaxis, recurrent chronic sinusitis and increased sinus pressure) were judged to be possibly unrelated to the device and all 5 events resolved without clinical sequelae. No patients withdrew due to an adverse event and no deaths occurred in this clinical study. There were no serious adverse events in the study that were related to the implant.

Effectiveness Results
The analysis of effectiveness was based on the 67 evaluable patients at the 30 day time point.

The primary efficacy endpoint was met. The rate of Post-Operative Intervention was 62.7% on the control sides compared to 38.8% on the treatment sides. This difference was statistically significant (p=0.0070) and represented a 38% relative reduction in Post-Operative Interventions.

Statistically significant reductions in the need for postoperative interventions, need for oral steroid intervention, need for surgical intervention, inflammation scores and rate of occlusion/restenosis were observed at day 30 as determined by clinical investigators. The implant delivery success rate was 100%, as evaluated by clinical investigators.

The incidence of adverse events was consistent with those seen in prior studies for the PROPEL drug-coated sinus stents. The incidence of each individual AE type by side (control vs. drug-coated stent) was quite similar. Overall, review of the safety data reveals no significant concerns related to adverse events.

Subgroup Analyses
The following preoperative characteristics were evaluated for potential association with outcomes: use of topical steroids and the use of the PROPEL or PROPEL Mini in the ethmoid sinus. There were no confounding effects on the primary efficacy endpoint.

PROPEL® Countour Sinus Implant (7)
The applicant performed a pivotal clinical study (PROGRESS, Nova* cohort) to establish a reasonable assurance of safety and effectiveness of the use of the PROPEL Contour sinus implant following Functional Endoscopic Sinus Surgery (FESS) to maintain patency of the frontal sinus opening in patients with chronic sinusitis in the U.S.

The applicant also performed a feasibility clinical study (EXCEED) to confirm reasonable assurance of safety and effectiveness of the device following FESS to maintain patency of the maxillary sinus in patients with chronic sinusitis. Data from these clinical studies were the basis for the PMA approval decision. A summary of the clinical studies are presented in the following subsections.

**Note: The name of the device was formally changed from PROPEL "Nova" to "Contour" after the studies were completed. However, the "PROGRESS, Nova Cohort" study title will remain in use to refer to the study within the information below.*

Table 4: Characteristics of the Clinical Studies

Clinical Study	Study Design	Objective	Number of Sites	Number of Subjects
EXCEED	Prospective, single-arm, open label feasibility study	To assess the performance, safety, and initial signals of efficacy of the drug-eluting PROPEL Contour Sinus Implant when used in chronic sinusitis (CRS) patients undergoing sinus surgery of the peripheral (frontal, maxillary) sinus ostia.	2	15
PROGRESS Nova Cohort	Prospective, randomized, blinded, controlled, multicenter pivotal study utilizing an intra-patient control design	To assess the safety and efficacy of the PROPEL Contour Sinus Implant when placed in the frontal sinus opening following frontal sinus surgery in patients with CRS	12	80

PROGRESS, Nova Cohort

Study Design

Patients were treated between July 7, 2015 and June 6, 2016. The database for this Panel Track Supplement reflected data collected through July 13, 2016 and included 80 patients. There were 12 investigational sites.

The PROGRESS clinical study (Nova cohort) was a prospective, randomized, blinded, concurrently controlled, multicenter study that enrolled 80 subjects at 12 U.S. sites. The objective of the study was to assess the safety and efficacy of the PROPEL Contour sinus implant in the frontal sinus opening following frontal endoscopic sinus surgery (ESS) to improve clinical outcomes and reduce the frequency of post-operative interventions, such as surgical lysis or adhesions, and use of oral steroids to control recurrent inflammation. The study utilized an intra-patient control design to assess the safety and effectiveness of the PROPEL Contour sinus implant compared to endoscopic sinus surgery alone with standard post-operative care. Subjects returned for follow-up evaluations over a total of 90 days. Results from the PROGRESS Nova Cohort study are presented here.

The rationale for selection of endoscopic sinus surgery alone as the choice of control was to compare the outcomes of stenting to the current standard of care. The patient underwent

bilateral endoscopic frontal sinus surgery following which only the treatment side received the PROPEL Contour sinus implant.

Use of an intra-patient control was selected as this study design minimizes variability that would be inherent in a parallel patient group design – most notably, variability introduced by concomitant medication usage. To eliminate the potential for bias in endoscopic grading, implants were removed at Day 21 and a blinded sinus surgeon independently graded the Day 30 endoscopic videos.

The primary efficacy endpoint of reduction in need for post-operative interventions was selected to provide evidence of a clinically meaningful patient benefit to clearly demonstrate the contribution of a mometasone furoate coated implant in the frontal sinus opening.

Pre-Specified Statistical Analysis Plan
The primary effectiveness hypothesis was that the PROPEL Contour sinus implant would reduce the need for Post-Operative Interventions at Day 30 compared to the control.

Follow-up Schedule
Baseline evaluations included a routine history and physical exam, ENT-HNS evaluation and CT scan to confirm chronic rhinosinusitis diagnosis (if not performed within past 6 months) and candidacy for sinus surgery. Follow-up assessments occurred prior to hospital discharge or clinic release and at post-operative Days 7, 21, 30 and 90.

The follow-up assessments included independent, blinded endoscopic examinations and CT outcomes assessed at Day 30 and Day 90 visits, respectively. On-site investigators conducted endoscopic examinations at all time points. At Day 21, the implant or its remnants were to be removed to allow for blinded review of video endoscopies at the Day 30 visit. Adverse events and serious adverse events were recorded and tabulated through day 30 and 90. Where possible and if applicable, adverse events were localized to a sinus location.

Clinical Endpoints
The primary efficacy endpoint was the reduction in need for Post-Operative Interventions at Day 30, as determined from video-endoscopies reviewed by a panel of three independent blinded sinus surgeons. Post-Operative Intervention was a composite endpoint that included:

- Surgical Intervention required to debride obstructive adhesions or scar tissue formation in the frontal sinus opening and/or
- Oral Steroid Intervention warranted to resolve recurrent inflammation or polypoid edema in the frontal recess/ frontal sinus opening.

Secondary efficacy endpoints pertaining to the frontal sinus opening included endoscopic assessment of adhesions/scarring, inflammation, polypoid tissue changes, sinus patency (including ostial diameter) and the need for surgical and oral steroid interventions to preserve sinus patency.

The safety endpoint was assessment of adverse events and serious adverse events Day 90.

To be considered successful, the PROGRESS Study needed to pass the primary efficacy hypothesis. The hypothesis is that the drug-coated implant reduces the need for post-operative interventions at Day 30 compared to the control.

Accountability of PMA Cohort
A total of 80 patients were enrolled in the study and 79 completed the follow-up visits through Day 90, representing a follow-up rate of 98.8%. No patient required termination from the study due to an adverse event through Day 90. The efficacy analyses were based on the intent-to-treat (ITT) population, which consists of all randomized patients who underwent implant placement.

Study Population Demographics and Baseline Parameters
The demographics of the study population are typical for a sinus implant study performed in the U.S. The study population consisted of 66.3% males, and the mean age was 49.5 years. At baseline, 55.0% patients had polypoid edema (grade 2) in the frontal recess/ frontal sinus opening, 45.0% patients had asthma; 8.8% patients had aspirin intolerance/allergy and 6.3% patients had Samter's Triad. The mean baseline total Lund-Mackay (L-M) score was 14.8, and 51.3% patients underwent at least 1 prior ESS. Control and treatment sides were well balanced with respect to mean L-M CT stage (7.4 control vs. 7.4 treatment side). All patients underwent bilateral frontal sinus surgery followed with implant placement on 1 randomized side.

Safety Results
The analysis of safety was based on the intent-to-treat population in the Nova cohort of 80 patients available for the 90 day evaluation.

Adverse effects: Sinusitis (acute and chronic) and headache were the most frequently reported AEs, in 16 (20.0%) patients and 5 (6.3%), respectively. Three adverse events (headache, epistaxis, acute sinusitis) were judged by clinical investigators as having an indeterminate relationship to the implant and these events resolved without sequelae. No patients withdrew due to an adverse event, and no deaths occurred in this clinical study. There were no serious adverse events in the study that were related to the implant.

Effectiveness Results
The analysis of effectiveness was based on the 61 evaluable patients at the 30 day time point.

The primary efficacy endpoint was met. The rate of Post-Operative Intervention was 32.8% on the control sides compared to 11.5% on the treatment sides. This difference was statistically significant (p=0.0023) and represented a 65% relative reduction in the need for Post-Operative Interventions.

Statistically significant reductions in the need for post-operative interventions, need for surgical intervention, inflammation scores and rate of occlusion/restenosis were observed at day 30 as determined by clinical investigators. The implant delivery success rate was 100%.

The incidence of adverse events was consistent with those seen in prior studies for the PROPEL drug-coated sinus stents. The incidence of each individual AE type by side (control vs. drug-coated stent) was quite similar. Overall, review of the safety data reveals no significant concerns related to adverse events.

Subgroup Analyses
The following preoperative characteristics were evaluated for potential association with outcomes:

- Usage of intranasal steroid sprays prior to 30 days,
- Presence of PROPEL or PROPEL Mini Sinus Implants in the ethmoid sinuses,
- Usage of intranasal steroid sprays prior to 30 days AND Presence of Propel or Propel Mini Sinus Implants in the ethmoid sinuses

There were no confounding effects on the primary efficacy endpoint.

Pediatric Extrapolation
In this premarket application, existing clinical data was not leveraged to support approval of a pediatric patient population.

EXCEED
The EXCEED study was a prospective, single-arm, open label feasibility study that enrolled 15 subjects at 2 study sites in the United States. The objective of the study was to assess the performance, safety and initial signals of efficacy of the drug-eluting PROPEL Contour sinus implant when used in chronic rhinosinusitis patients undergoing sinus surgery of the peripheral sinus ostia. Eligible patients underwent endoscopic sinus surgery (ESS) that included enlargement of peripheral sinus ostia using traditional surgical technique and/or balloon dilation in the operating room or office setting. Following successful ESS, subjects were implanted with at least 2 and a maximum of 4 PROPEL Contour sinus implants in the frontal and/or maxillary sinuses.

Follow-up Schedule
Subjects returned for follow-up visits at Days 7, 30, 45 and 90. Follow-up assessments included endoscopic examinations, objective endoscopic grading and patient-reported outcomes.

Clinical Endpoints
The primary efficacy endpoint of this study was implant delivery success which was defined as successful access and deployment of the PROPEL Contour sinus implant into the target sinus ostium within 2 attempts.

Secondary efficacy endpoints included endoscopic measures of ostial patency, degree of inflammation and polypoid edema and patient reported outcomes of Sino-Nasal Outcomes Test 22 (SNOT-22) scores.

The primary safety endpoint was based upon the frequency of serious unanticipated adverse device effects (UADEs). The study was considered successful if no serious UADEs occurred.

Accountability of PMA Cohort
Sixteen patients were enrolled between June 25, 2014 and September 16, 2014 at 2 investigational centers. One patient did not meet the eligibility criteria. Of the 16 patients enrolled in the study, 15 met final eligibility criteria. PROPEL Contour sinus implant placement was intended in 15 patients and involved 47 sinuses. Two sinuses to be treated in the office setting were not amenable to implant placement.

One patient receiving an implant in the office setting withdrew consent following the Day 7 visit due to the long travel distance to the study site. Overall study visit compliance was 100% (15/15) at 7 days, 100% (14/14) at 30 days, 86% (12/14) at 45 days, and 100% (14/14) at 90-days post procedure.

Study Population Demographics and Baseline Parameters
All 15 subjects and 45 sinuses were included in the safety analyses. The mean age was 50.6 (SD 13.24) years, and most subjects (86.7%) were male, white (86.7%), and not Hispanic or Latino (66.7%). Seven subjects (46.7%) had prior ESS. Nine subjects (60.0%) had allergic rhinitis, 4 (26.7%) had asthma, and 1 (6.7%) had aspirin intolerance/allergy. The mean total Lund-Mackay (L-M) score at screening was 12.7 (SD 5.57), with a mean L-M score for the frontal sinuses of 2.5 (SD 1.19), and 2.3 (SD 0.98) for the maxillary sinuses.

Ten of the 15 subjects were treated in the office setting and 5 were treated in the operating room setting. In the frontal sinuses, sinus surgery was mainly performed using balloon dilation alone (92.3%). In the maxillary sinuses, sinus surgery was performed using balloon dilation alone (81.0%) or balloon dilation with rigid surgical instrumentation (19.0%). Baseline endoscopic assessments were performed prior to sinus surgery using balloon dilation and implant placement in all subjects.

Safety Results
There were no serious unanticipated AEs and the study primary safety endpoint was met.

Adverse effects: A total of 12 adverse events of any type were reported in 9 subjects (60.0%). None of the adverse events were implant-related. Most adverse events were considered related to morbid or comorbid conditions (41.7%), or the surgical/endoscopic procedure (33.3%). One adverse event was considered serious and related to the morbid/co-morbid conditions and resolved within 30 days.

Effectiveness Results

The study results showed an overall implant delivery success rate of 97.8% (100% in frontal sinuses; 95.2% in maxillary sinuses), demonstrating that the primary performance endpoint was met. Observed endoscopic improvements at Day 90 included a 46.8% increase in ostial patency, a 75.0% reduction in polypoid edema, a 19% reduction in grade 2 and 3 adhesion/scarring, and a 38.1 mm decrease in inflammation score. The mean total SNOT-22 score decreased from 1.94 (SD 0.672) at baseline to 0.94 (SD 0.909) at Day 90, resulting in a treatment effect size of 1.09*.

*This represents the normalized score that was obtained by dividing the total score (ranging from 0 – 110) by the number of questions answered. The total SNOT-22 score decreased from 42.6 (SD 14.9) at baseline to 20.6 (SD 19.3) at Day 90, resulting in a treatment effect size of 1.14.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	31237, 31299
HCPCS Codes	C1874, C2625, J3490, J7402, S1091

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
01/01/2026	New medical document originating from SUR706.001 Nasal and Sinus Surgery. The Coverage for Drug-Eluting Sinus Implants has changed. Drug-Eluting Sinus Implants may be considered medically necessary when criteria stated in the Coverage are met. Placement of a mometasone furoate sinus implant is considered experimental, investigational and/or unproven for all other non-Food and Drug Administration approved uses.