

CLINICAL DATA SUMMARY: PROPEL[®] STEROID-RELEASING IMPLANT

PROPEL is the first and only product in sinus surgery clinically proven with Level 1-A evidence to maintain surgical results.¹

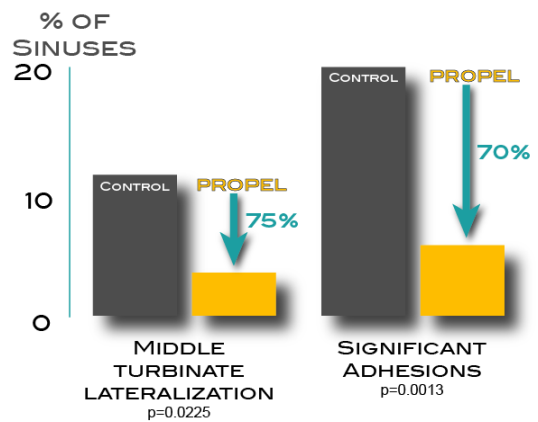
PROPEL provides meaningful benefits to patients:

PROPEL maintains the opening created during surgery by reducing post-operative scarring, inflammation, polyposis and middle turbinate lateralization. Reducing such scarring and inflammation is essential to improve long-term outcomes and reduce the need for revision surgery^{2,3}

**PROPEL VS SPACING ALONE
REDUCTIONS IN POST-OPERATIVE INTERVENTIONS**



Meta-Analysis Panel grading



Meta-Analysis Real-time grading

Safety & Efficacy – Evaluated in Three Prospective Multi-Center Clinical Trials totaling 205 patients

- 1** A prospective, randomized, controlled, double-blind **Pilot study⁴**, recognized with the 2010 Maurice Cottle Research Award honoring best clinical or basic science by the American Rhinologic Society

- 2** The **ADVANCE** single-cohort study⁵ assessed safety, endoscopic outcomes and demonstrated improved patient symptom scores out to six months

- 3** The **ADVANCE II** randomized, controlled, double-blind clinical trial⁶, which included review by an independent panel of surgeons

All three trials assessed the safety and efficacy of controlled delivery of mometasone furoate to the ethmoid sinus mucosa via dissolvable implants in chronic rhinosinusitis (CRS) patients undergoing functional endoscopic sinus surgery (FESS).

Safety Established in Clinical Studies:

- Ocular safety demonstrated: No clinically significant changes from baseline in intraocular pressure or lens opacities occurred
- Systemic safety demonstrated: No evidence of systemic steroid exposure or adrenal-pituitary axis suppression

Summary of Clinical Publications

Pilot Study

Murr AH, Smith TL, Hwang PH, et al. *Int Forum Allergy Rhinol.* 2011; 1:23–32.

- Prospective, multi-center, randomized, double-blind trial comparing PROPEL to a non-steroid eluting implant (n=50)
- Broad patient population: 70% polyp patients, 37% prior sinus/nasal surgery, mean Lund-MacKay = 13.4
- Statistically significant reductions in adhesions, inflammation, and polyposis, which are predictors of positive long-term outcomes

The ADVANCE Study

Forwith KD, Chandra RK, Yun PT, et al. *Laryngoscope.* 2011; 121(11): 2473–2480.

- Real world study design: Single-cohort, open-label study (n=50)
- Broad patient population: 66% polyp patients, 28% prior sinus/nasal surgery patients, mean Lund-MacKay = 11.2
- FESS + Implants resulted in significant symptom reduction through 6 months using SNOT-22 & RSDI

The ADVANCE II Study

Marple BF, Smith TL, Han JK et al. *Otolaryngol Head Neck Surg.* 2012; 146(6) 1004-1011.

- Primary efficacy in this prospective, multicenter, randomized, double-blind trial was evaluated by an independent, blinded panel of surgeons (n=105)
- *PROPEL Sustained Steroid Release provides clinically meaningful benefits to patients:* Reduces the need for surgical intervention and oral steroids
- *PROPEL maintains sinus patency:* Reduces inflammation, adhesions and polyposis. Reducing such scarring and inflammation is essential to improve long-term outcomes and reduce the need for revision surgery^{2,3}

Meta-Analysis of 143 Pilot Study and ADVANCE II Patients

Han JK, Marple BF, Smith TL et al. *Int Forum Allergy Rhinol.* 2012; 2(4) 271-279.

- *First and only Level 1-A evidence in support of an ENT product*
- The Meta-analysis pooled efficacy data for the 143 patients from the two prospective, controlled, randomized, double-blind, multi-center trials with similar demographics and endpoints
- *Localized controlled steroid delivery confers meaningful benefits:* Reduces scarring, inflammation, polyposis and middle turbinate lateralization, essential to avoiding the need for revision surgery
- *PROPEL improves surgical outcomes:* 35% reduction in need for post-operative medical/surgical therapies which may mean shorter and less painful post-op visits.
- Reduces need for oral steroids by 40%, a meaningful benefit of local sustained steroid release.

Additional Publications

Lee JT, Han JK. Sinus Implants for chronic rhinosinusitis: technology evaluation. *Expert Opin. Drug Deliv.* 2013; 10(12): 1735–1748.

Wei CC, Kennedy DW. Mometasone implant for chronic rhinosinusitis. *Medical Devices: Evidence and Research.* 2012; 5:75-80.

Kennedy DW. The PROPEL steroid releasing bioabsorbable implant to improve outcomes of sinus surgery. *Expert Review of Respiratory Medicine.* 2012; 6(5):493-498.

Ramakrishnan VR, Kennedy DW. Advances in the surgical management of chronic sinusitis and nasal polyps. *Current Allergy and Asthma Reports.* 2011; 11(3): 220-229.

Li PF, Downie D, Hwang PH. Controlled steroid delivery via bioabsorbable stent: Safety and performance in a rabbit model. *American Journal of Rhinology & Allergy.* 2009; 23(6): 591-596.

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1. Han JK, Marple BF, Smith TL et al. *Int Forum Allergy Rhinol.* 2012 ; 2 :271-279.
 2. Kennedy DW, Wright ED, Goldberg AN. *Laryngoscope.* 2000;110:29–31.
 3. Kennedy DW. *Expert Review of Respiratory Medicine.* 2012; 6(5):493-498.
 4. Murr AH, Smith TL, Hwang PH, et al. *Int Forum Allergy Rhinol.* 2011;1:23–32.
 5. Forwith KD, Chandra RK, Yun PT, Miller SK, Jampel HD. *Laryngoscope.* 2011;121:2473–2480.
 6. Marple BF, Smith TL, Han JK et al. *Otolaryngol Head Neck Surg.* 2012; 146(6) 1004-1011.

The PROPEL sinus implant is intended for use following ethmoid sinus surgery to maintain patency. For more information consult your physician or visit www.intersectENT.com to view prescribing information including indications, contraindications, warnings, precautions and adverse events. Caution: Federal law (USA) restricts this product to sale by or on the order of a physician.