Clinical Data Summary:

PROPEL™ Steroid-Releasing Implant

Safety and efficacy of the PROPEL™ Steroid-Releasing Implant have been studied in three prospective clinical trials conducted in the United States enrolling a total of 205 patients.

1. A randomized, controlled, double-blind Pilot study[1], recognized with the 2010 Maurice Cottle Research Award honoring best clinical or basic science by the American Rhinologic Society
2. The ADVANCE single-cohort study[2] that assessed safety, endoscopic outcomes and patient symptoms to six months
3. The ADVANCE II randomized, controlled, double-blind clinical trial[3], which included review by an independent panel of surgeons.

- Additionally, a meta-analysis[4] of the Pilot and ADVANCE II studies was conducted providing the first Level 1A evidence in ENT. PROPEL is the only product used in sinus surgery to be supported by this level of evidence.

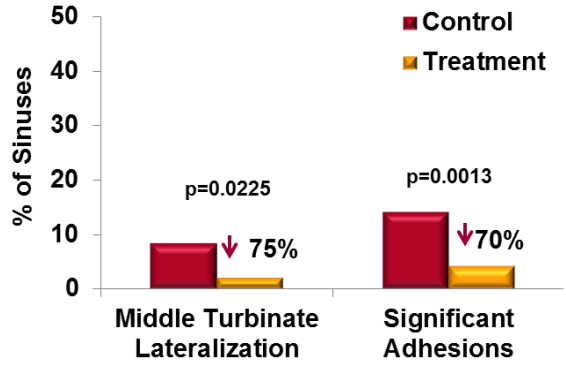
All three trials assessed the safety and efficacy of controlled delivery of mometasone furoate to the ethmoid sinus mucosa via dissolvable implants in chronic rhinosinusitis (CRS) patients undergoing functional endoscopic sinus surgery (FESS).

Intersect ENT's PROPEL clinical program has demonstrated meaningful benefits to patients:

- In a broad patient population, PROPEL maintains patency by reducing post-operative scarring, inflammation, polyposis and middle turbinate lateralization. Reducing these post-op factors is proven to improve long term outcomes and reduce the need for revision surgery[5]
- Additionally, PROPEL reduces need for post-operative medical and surgical therapies by 35%, which may mean shorter and less painful post-op visits. In particular, the analysis demonstrated a 40% reduction in need for oral steroid interventions.

	Relative Reduction	*p value*
Need for Medical / Surgical Tx	**↓ 35%**	**0.0008**
Need for Oral Steroids	**↓ 40%**	**0.0023**
Polyposis	**↓ 46%**	**<0.0001**

Meta-Analysis Panel grading



Meta-Analysis Real-time grading

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

Intersect ENT | 1555 Adams Drive | Menlo Park, CA 92025 | 650.641.2100
www.PROPELOPENS.com

Summary of Clinical Publications

Pilot Study

Murr AH, Smith TL, Hwang PH, et al. Int Forum Allergy Rhinol. 2011.

- Prospective, multi-center, randomized, double-blind trial comparing PROPEL to a non-drug releasing stent enrolling 50 patients
- Challenging patient population: 70% polyp patients, 37% prior sinus/nasal surgery, mean Lund-MacKay of 13.4
- Statistically significant reductions in presence of adhesions, inflammation, and polyposis, a predictor of positive long-term outcomes

The ADVANCE Single-Cohort Study

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

- Real world study design**:** Single-cohort, open-label study of 50 patients
- Challenging patient population**:** 66% polyp patients, 28% prior sinus/nasal surgery patients, mean Lund-MacKay of 11.2
- FESS + Implants resulted in Symptom reduction through 6 months**:** Significant reductions in symptoms were reported by patients through 6 months (using SNOT-22 & RSDI)
- Consistent with the PROPEL arm of the Pilot study**:** Low rates of adhesions and polyp formation observed

The ADVANCE II Randomized, Double-Blind Pivotal Clinical Trial

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 U.S. clinical trial was evaluated by an independent blinded panel of surgeons
- *PROPEL Sustained Steroid Release provides clinically meaningful benefits to patients:* Reduces the need for surgical intervention and oral steroids in the post-FESS period
- *PROPEL maintains sinus patency:* Reduces inflammation, adhesions and polyposis. Reducing these post-op issues is correlated with reduced need for revision surgery

Meta-Analysis of 143 Pilot Study and ADVANCE II Patients

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

- The Meta-analysis pooled 143 patients from the Pilot study and ADVANCE II results, which were both prospective, controlled randomized, double-blind, multi-center clinical trials with similar demographics and endpoints
- First Level 1-A evidence in support of an ENT product
- PROPEL's localized controlled steroid delivery confers meaningful benefits: Reduces adhesions, frank polyposis and middle turbinate lateralization. Reducing these post-op factors is proven to reduce the need for revision surgery. PROPEL provided a 46% reduction in frank polyposis
- PROPEL improves surgical outcomes: Reduces need for post-operative medical and surgical therapies by 35%, which may mean shorter and less painful post-op visits.
- The analysis demonstrated a 40% reduction in need for oral steroid interventions.

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

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