PROPEL®
MOMETASONE FUROATE IMPLANT

intersect ENT

PROPEL STEROID-RELEASING IMPLANT

Opens. Delivers. Maintains.

Intersect ENT has developed the PROPEL dissolvable implant for chronic sinusitis patients undergoing sinus surgery; the first and only sinus surgery product backed by Level 1-A evidence. PROPEL is the first of a new category of products offering localized, controlled drug delivery directly to the sinus tissue. Inserted by a physician to maintain the surgical opening, the spring-like implant expands to prop open the ethmoid sinus and gradually delivers an advanced corticosteroid (mometasone furoate) with anti-inflammatory properties directly to the sinus lining as the implant dissolves.

The PROPEL system has been clinically proven to prevent obstruction of the ethmoid sinus following surgery. The result is improved post-operative outcomes, reducing the need for additional surgical procedures such as adhesion lysis and systemic steroids.

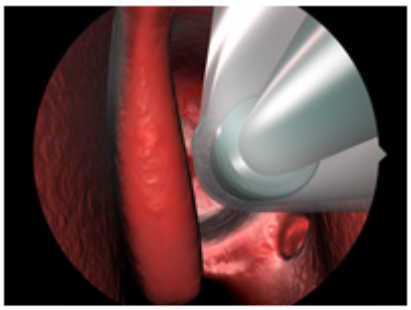
ENT Surgeons can learn more about the PROPEL mometasone furoate implant by contacting Intersect ENT.

Click here for Instructions for Use.

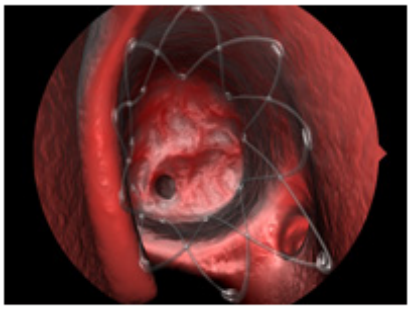
Caution: Federal law (USA) restricts this product to sale by or on the order of a physician.

HOW IT WORKS

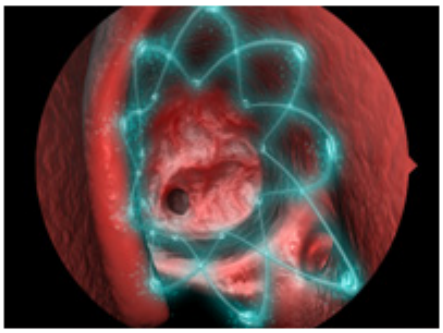
Innovative yet intuitive.



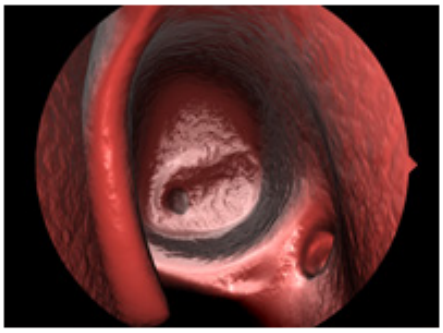
PROPEL Delivery System is directed to the open surgical cavity.



The PROPEL implant's spring-like design conforms to patient's unique anatomy and props open the sinus.



Sustained, local release of mometasone furoate over 30 days.*



Eventually dissolves.

The PROPEL system leverages Sustained Release Technology, which allows for local, sustained drug delivery directly to the sinus mucosa. Mometasone furoate is embedded in a highly customized polymer, which controls the release of drug over time as the implant dissolves. The self-expanding nature of PROPEL ensures the implant props open the cavity and apposes the tissue to maximize targeted drug delivery.

* Data on file

CLINICAL DATA

PROPEL the first and only sinus surgery product backed by Level 1-A evidence.

Safety and efficacy of the PROPEL Steroid-Releasing Implant has been studied in three prospective clinical trials conducted in the United States, with a total of 205 patients enrolled.

* A randomized, controlled, double-blind Pilot study, recognized with the 2010 Maurice Cottle Research Award honoring best clinical or basic science by the American Rhinologic Society (ARS)

- The ADVANCE single-cohort study that assessed safety, endoscopic outcomes and patient symptoms to 6 months
- The ADVANCE II randomized, controlled, double-blind clinical trial, 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). These rigorously designed studies provide an unparalleled level of clinical evidence upon market release for a sinus product. PROPEL brings clinically and statistically significant benefits to patients.

All studies were conducted in a challenging patient population:

- > 60% polyps at baseline
- > 30% prior sinus/nasal surgery
- > 12 Mean Lund-Mackay CT stage

OUR CLINICAL PROGRAM HAS SHOWN THAT PROPEL:

- Maintains patency by reducing post-operative adhesions, inflammation, polyposis[11] & middle turbinate lateralization; Reducing these post-op factors is proven to improve long term outcomes and reduce the need for revision surgery[12]
- Decreases need for post-operative medical and surgical therapies, including adhesion lysis and oral steroid therapy

Click here to for a visual representation of Propel's clinical program results.

SAFETY:

- 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

META-ANALYSIS:

The Meta-analysis pooled the Pilot study and ADVANCE II results, which were both prospective, controlled randomized, double-blind, multi-center clinical trials with similar demographics and endpoints. The pooled analysis included 143 patients, who served as their own controls. The analysis assessed PROPEL's ability to preserve sinus patency and reduce medical and surgical interventions after FESS.

- First Level 1-A evidence demonstrating the benefit of localized steroid release in the post-FESS period
- 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[12] PROPEL provided a 46% reduction in frank polyposis.[11]
- 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[11].

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11 Han JK, Marple BF, Smith TL et al. Effect of steroid-releasing sinus implants on post-operative medical and surgical interventions. *Int Forum Allergy Rhinol.* 2012; 2:271-279.

12 Kennedy et al. *Laryngoscope.* 110 (Suppl. 94):29–31, 2000.

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

14 Forwith KD, Chandra RK, Yun PT, et al. *Laryngoscope*, 121:2473–2480, 2011.

All of the above information was provided by the Propel Website:

http://www.intersectent.com/index.html