

FACT SHEET:

PROPEL[®] STEROID-RELEASING IMPLANT

Chronic Sinusitis: One of America's Most Common Health Conditions

31 million people are afflicted with chronic sinusitis each year, making it one of the most common health conditions in the United States.¹

The sinuses are air-filled cavities located within the bones around the nose and eyes that allow for natural ventilation and drainage. In Chronic Sinusitis, the sinus linings become inflamed, blocking the natural drainage passageways and leading to chronic infections and nasal obstruction.

Patients with chronic sinusitis often suffer from debilitating symptoms such as facial pain or pressure, nasal congestion and difficulty breathing, discolored nasal discharge, loss of smell and taste, headache, fatigue and depression.

A Need to Improve Treatment Outcomes

Chronic sinusitis often requires a complex combination of surgical and medical treatments. When sinusitis does not respond to medications, surgery to enlarge the openings that drain the sinuses may be an option.

Each year, 500,000 patients undergo ethmoid sinus surgery to treat the condition.² Although sinus surgery is effective, the majority of patients experience recurrent symptoms within the first year; as many as 25 percent then undergo revision surgery due to recurrent obstruction of the sinus cavity.³

Chronic Sinusitis Patients Have A New Weapon - PROPEL

The goal of surgical treatment for chronic sinusitis is to enlarge the inflamed or obstructed sinus passageways. Post-surgery check-ups are required to inspect the sinus cavities to monitor for inflammation and scarring and treat accordingly with surgery and/or oral steroids.

The dissolvable PROPEL Steroid-Releasing Implant is the first in a new category of products offering localized, controlled delivery of steroid directly to the sinus tissue to maintain the openings created in surgery.

Applying principles of coronary drug-eluting stents to sinusitis sufferers, the spring-like implants gradually deliver an advanced steroid with anti-inflammatory properties (mometasone furoate) directly to the sinus lining, then dissolve into the body following endoscopic sinus surgery. The result is improved surgical outcomes, reducing the need for additional surgical procedures and for systemic steroids, which can have serious side effects.

Three rigorous clinical trials⁴ have demonstrated that the implant is safe and maintains the results of sinus surgery by propping open the sinus cavities and decreasing post-operative scarring and inflammation. Reducing these factors is proven to improve long-term outcomes⁵ and to reduce the need for repeat surgery and oral steroids, which can have serious side effects. PROPEL is the only product used in sinus surgery to be supported by level 1-A evidence.

¹ National Health Interview Survey 2006. CDC National Center for Health Statistics. Series 10 Number 235.

² Rosenfeld et al., *Oto-HNS*. 2007; 137:S1-S31.

³ Schaitkin BM, May M, Shapiro A: et al., *Laryngoscope*. 1993; 103: 1117-20.

⁴ Pilot study results: Murr AH, Smith TL, Hwang PH, et al. *IFAR*. 2011;1:23-32.; *ADVANCE II clinical trial*: Marple BF, Smith TL, Han JK et al. *Otolaryngol Head Neck Surg*.2012; 146(6) 1004-1011.; *Meta-analysis*: Han JK, Marple BF, Smith TL et al *IFAR*. 2012; 2 :271-279.

⁵ Kennedy DW, Wright ED, Goldberg AN. *Laryngoscope*. 2000;110:29-31.

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 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.

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