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. Sometimes the sinus linings become inflamed, blocking the natural drainage passageways and leading to chronic infections and nasal obstruction. This condition is called chronic sinusitis.

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]

PROPEL Controlled Drug Delivery Implant Offers Relief for Patients with Chronic Sinusitis

The goal of surgical treatment for chronic sinusitis is to enlarge the inflamed or obstructed sinus passageways. Post-surgery check-ups are required to clean the sinus cavities and ensure that they are open, healing well and without scarring.

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.

Inserted by the physician to maintain the surgical opening, the self-expanding nature of the spring-like PROPEL ensures the implant props open the cavity, apposing the tissue to maximize targeted drug delivery directly to the sinus mucosa. Mometasone furoate, a corticosteroid with anti-inflammatory properties, is embedded in a highly customized polymer that controls the release of drug over time as the implant dissolves.

Three rigorous clinical trials[4] have demonstrated that the implant is safe and maintains the results of sinus surgery by decreasing post-operative adhesions, inflammation, polyposis and middle turbinate lateralization. Reducing these factors is proven to improve long-term outcomes[5] 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.

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[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. Int Forum Allergy Rhinol. 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. Int Forum Allergy Rhinol. 2012; 2:271-279.
[5] Kennedy DW, Wright ED, Goldberg AN. Laryngoscope. 2000;110:29–31.