



## Real-World Evidence Study Demonstrates Intersect ENT's PROPEL® Sinus Implant Reduces Healthcare Resource Utilization

January 25, 2022

*Data from first-of-its-kind study published in Current Medical Research and Opinion*

*Patients receiving PROPEL® following endoscopic sinus surgery had statistically significant lower healthcare resource utilization over a postoperative period of 18 months, including all-cause otolaryngologist, ER/urgent care and outpatient visits, as well as sinus-related endoscopies*

MENLO PARK, Calif.--(BUSINESS WIRE)--Jan. 25, 2022-- Intersect ENT®, Inc. (Nasdaq: XENT), a global ear, nose and throat ("ENT") medical technology leader dedicated to transforming patient care, today announced positive results of an observational, cohort study using real-world evidence (RWE) data from adult patients with chronic rhinosinusitis (CRS) with or without nasal polyps who underwent endoscopic sinus surgery (ESS). Study results demonstrate that patients receiving PROPEL® sinus implants following sinus surgery had lower healthcare resource utilization (HCRU) over a postoperative period of 18 months compared with patients who did not receive an implant. These results from the first-of-its-kind study using RWE are published online in [Current Medical Research and Opinion](#).

CRS causes severe symptoms, leading to patient discomfort, poor quality of life and added HCRU. While ESS can improve CRS symptoms, post-surgical scarring, adhesion formation and early polyp recurrence can compromise surgical outcomes. Intersect ENT's PROPEL sinus implants uniquely provide mechanical stenting of a patient's sinuses while providing localized delivery of the corticosteroid mometasone furoate directly to healing sinus tissue, features that have been shown previously to improve outcomes after sinus surgery.<sup>1-3</sup>

"As one of the first observational studies to use real-world evidence to assess healthcare resource utilization in patients with chronic sinusitis who underwent endoscopic sinus surgery, the results provide important longitudinal data that can support the use and reimbursement of the PROPEL sinus implants," said Thomas A. West, President and Chief Executive Officer of Intersect ENT. "The data show that patients receiving PROPEL had statistically significant lower healthcare resource utilization with respect to all-cause otolaryngologist, urgent care and outpatient visits, as well as sinus-related endoscopies, with a trend toward a reduction in revision sinus surgeries for the 18-month period following sinus surgery. These results clearly demonstrate a positive impact of the PROPEL sinus implants that translates into improved economic outcomes across the episodes of care for patients with chronic sinusitis undergoing sinus surgery. We intend to incorporate these findings into our ongoing discussions with payers as we strive to increase patient and physician access to PROPEL in appropriate populations."

The study examined claims, electronic medical records and other data from patients with CRS with or without nasal polyps who underwent ESS between 2014 and 2019 and had at least 18 months of data before and after surgery. Patients receiving PROPEL sinus implants (N = 1,983) were matched to patients who did not receive implants (N = 1,983). The matched cohorts were similar with respect to age, sex, race, year of surgery, and insurance type. However, more patients in the implant cohort underwent surgery involving multiple sinuses than the non-implant cohort (94.8% vs. 85.1%), suggesting that patients in the implant cohort may have had greater disease severity than those in the non-implant cohort. Key study findings during the 18 months of post-surgical follow-up revealed that patients in the implant cohort compared to the non-implant cohort had a statistically significant reduction in:

- All-cause otolaryngologist visits (47.3% vs. 59.6%,  $p < 0.001$ )
- All-cause ER/urgent care visits (9.2% vs. 11.8%,  $p = 0.007$ )
- All-cause outpatient visits (94.3% vs. 96.6%,  $p < 0.001$ )
- Sinus-related endoscopies (39.1% vs. 43.8%,  $p = 0.003$ )

Although not statistically significant, fewer patients in the implant cohort underwent repeat surgery compared to the non-PROPEL cohort (4.6% vs. 5.3%,  $p = 0.273$ ).

It should be noted that RWE studies cannot definitively establish causality and are designed to evaluate associations. Study limitations included: no identification of the specific sinuses in which implants were placed, imaging studies were limited to sinus related procedures (it is possible that imaging was completed on non-CRS related sinus issues), a lack of medication data available to allow for a complete assessment of medications used to treat CRS patients, and incomplete data capture may have occurred during the study period.

"These real-world evidence results are compelling, especially given the potentially higher disease severity among patients who received PROPEL," said James Kallman, MD, FACS lead author on the paper. "Due to this potential difference, the results may underestimate the full impact of PROPEL on healthcare resource utilization and revision surgery. The results indicate that PROPEL can reduce multiple aspects of healthcare resource utilization in chronic rhinosinusitis patients, which may translate into a reduction in these patients' overall healthcare costs. Combined with the previously demonstrated clinical benefit that PROPEL can provide to patients, these real-world evidence results provide compelling evidence to support the use of PROPEL in patients undergoing endoscopic sinus surgery."

### About Intersect ENT

Intersect ENT is a global ear, nose and throat medical technology leader dedicated to transforming patient care. The Company's steroid releasing implants are designed to provide mechanical spacing and deliver targeted therapy to the site of disease. In addition, Intersect ENT is continuing to expand its portfolio of products based on the Company's unique localized steroid releasing technology and is committed to broadening patient access to less invasive and more cost-effective care. In October 2020, Intersect ENT acquired Fiagon AG Medical Technologies, a global leader in electromagnetic surgical navigation solutions with an expansive portfolio of ENT product offerings, including the VenSure™ sinus dilation balloon,

which is FDA-cleared in the U.S., and the CUBE™ Navigation System, that complement the Company's PROPEL® family of sinus stents and SINUVA® (mometasone furoate) sinus implants and extend its geographic reach.

For additional information on the Company or the products including risks and benefits, please visit [www.IntersectENT.com](http://www.IntersectENT.com). For more information about PROPEL® (mometasone furoate) sinus implants, SINUVA® (mometasone furoate) sinus implant, and VenSure™ and Cube™, please visit [www.PROPELOPENS.com](http://www.PROPELOPENS.com), [www.SINUVA.com](http://www.SINUVA.com) and [www.VenSureandCube.com](http://www.VenSureandCube.com).

Intersect ENT®, PROPEL® and SINUVA® are registered trademarks of Intersect ENT, Inc in the US and other countries. VenSure and CUBE have pending trademark applications.

### **Important Safety Information for the PROPEL Sinus Implant**

The PROPEL sinus implants are intended to maintain patency and locally deliver steroid to the sinus mucosa in patients ≥18 years of age following sinus surgery: PROPEL for the ethmoid sinus, PROPEL Mini for the ethmoid sinus/frontal sinus opening, and PROPEL Contour for the frontal/maxillary sinus ostia. Contraindications include patients with confirmed hypersensitivity or intolerance to mometasone furoate (MF) or hypersensitivity to bioabsorbable polymers. Safety and effectiveness of the implant in pregnant or nursing females have not been studied. Risks may include, but are not limited to, pain/pressure, displacement of the implant, possible side effects of intranasal MF, sinusitis, epistaxis, and infection. For full prescribing information see IFU at [www.IntersectENT.com/technologies/](http://www.IntersectENT.com/technologies/). Rx only.

### **Forward-Looking Statements**

This release contains forward-looking statements within the meaning of Sections 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We may, in some cases, use terms such as “look forward,” “confident,” “promises,” “predicts,” “believe,” “potential,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should,” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. These forward-looking statements are based on Intersect ENT's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation those related to the safety, efficacy and patient and physician adoption of the Company's products and therapies, the ability to obtain and maintain reimbursement codes for its products, the Company's ability to procure and maintain required regulatory approvals for our products, the Company's ability to grow and expand its business, as well as other risks detailed from time to time in Intersect ENT's filings with the Securities and Exchange Commission (SEC), including Intersect ENT's filings on Form 10-K and Form 10-Q available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)). Intersect ENT does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

<sup>1</sup> Han et al., *Int Forum Allergy Rhinol*. 2012;2:271-9.

<sup>2</sup> Smith TL, Singh A, Luong A, et al. *Laryngoscope*. 2016; 126:2659-64.

<sup>3</sup> Luong A, Ow RA, Singh A, et al. *JAMA Otolaryngol Head Neck Surg*. 2018;144:28-35.

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Source: Intersect ENT, Inc.