

# The PROGRESS Study

Landmark Clinical Research to Demonstrate Safety and Efficacy of  
the use of PROPEL Mini Steroid Releasing Implants Following  
Frontal Sinus Surgery

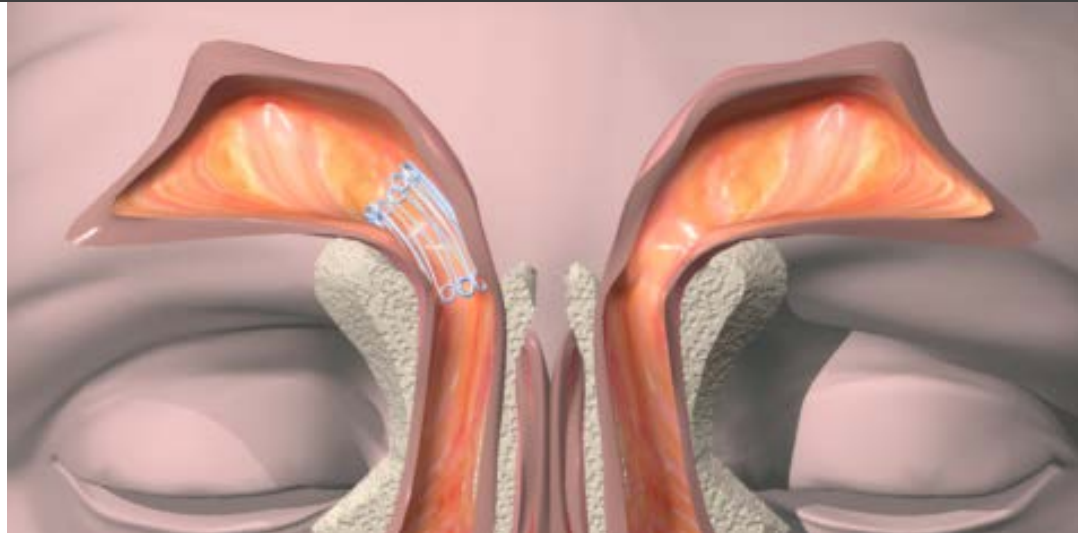
 **PROPEL**<sup>®</sup>  
m i n i  
MOMETASONE FUROATE IMPLANT

# Study Overview

The PROGRESS Study was a 80-patient prospective, randomized, controlled, blinded clinical trial. The study evaluated outcomes of frontal sinus surgery (using balloons and/or traditional instruments) with PROPEL Mini placement compared to the surgery alone with standard post-operative care.<sup>1</sup>

80 patients, 11 U.S. Sites

**Treatment side:**  
ESS + standard  
post-op care +  
PROPEL Mini



**Control side:**  
ESS + standard  
post-op care

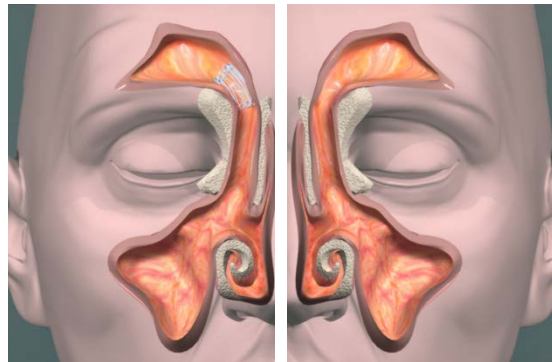
<sup>1</sup> Smith TL, Singh A, Luong A et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 126:2659–2664, 2016.

# Study Design

**Intra-patient control study design to evaluate the clinical outcomes of PROPEL Mini compared to surgery alone.**

## Treatment Side

- **PROPEL Mini Implant**
- Antibiotics – 10d course
- Saline irrigation as needed
- Debridement as needed
- Steroid sprays allowed at post-op day 14 as needed
- Oral steroids as needed



## Control Side

- Antibiotics – 10d course
- Saline irrigation as needed
- Debridement as needed
- Steroid sprays allowed at post-op day 14 as needed
- Oral steroids as needed

Note: Device was removed at Day 21 to facilitate blinded independent assessment at Day 30.

# Entry Criteria and Primary Endpoint

## Key Inclusion Criteria

- CRS confirmed by CT; defined as symptoms 12+ weeks
- Clinical indication for ESS including bilateral frontal sinus surgery. Confirmed by Frontal Lund-Mackay score of  $\geq 1$  on each side
- Successful frontal sinus enlargement using Draf II (A or B) dissection and/or balloon dilation, with minimum of 5-mm diameter opening created.

## Primary Endpoint

- Reduction in **need for post-operative interventions** at Day 30, by an independent, blinded surgeon based on video-endoscopy reviews.
- Post-operative intervention is a composite endpoint of either:
  - Surgical intervention required to debride adhesions or scar tissue formation
  - Oral steroid intervention warranted to resolve recurrent inflammation, edema and/or polyposis in the frontal recess/FSO

# Baseline Demographics and Characteristics

	<b>All Patients (N=80)</b>
Age, years	49.9
Male	57.5%
Prior ESS	51.2%
Hx of Asthma	37.5%
Hx of Aspirin Intolerance	7.5%
Current Smokers	11.3%

<b>Endoscopic Procedures Performed</b>	<b>Treatment Side</b>	<b>Control Side</b>
Frontal Sinusotomy, %	98.8	98.8
Anterior Ethmoidectomy, %	97.5	97.5
Posterior Ethmoidectomy, %	95.0	96.3
Instrumentation used:		
Rigid Surgical Instruments, %	63.8	63.8
Balloon Dilation only, %	1.3	1.3
Both, %	35.0	35.0

# PROPEL Mini Preserves Frontal Sinus Patency following Surgery<sup>1</sup>

## Outcomes of ESS + PROPEL Mini compared to ESS Alone at 30 days



**30 day outcomes maintained through 90 Day timepoint (p=0.0129)**

N=80 ITT intra-patient control, with N=67 evaluable patients with both sinuses available for composite. endpoint. Arrows indicates relative reductions at 30d.

\* Indicates Secondary Endpoint results judged by Clinical Investigator/Implanting Physician. P-values for secondary endpoints were not adjusted for multiplicity.

<sup>1</sup> Smith TL, Singh A, Luong A et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 126:2659–2664, 2016.

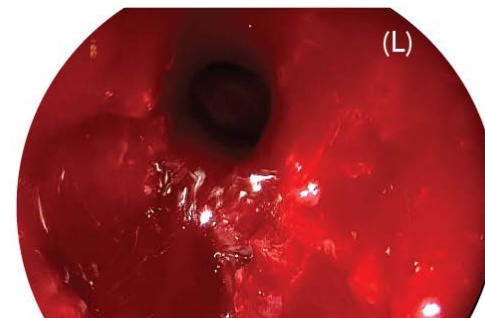
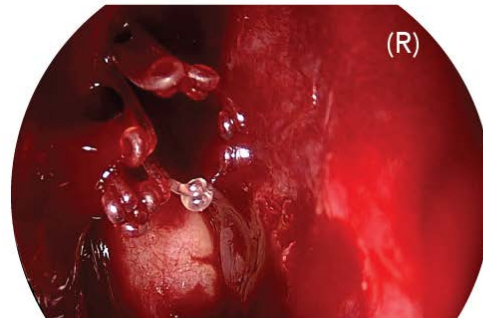
# Patient Outcome Following Frontal Sinus Surgery with PROPEL Mini

***PROPEL Mini is the first and only product clinically proven to improve outcomes of frontal sinus surgery<sup>1</sup>***

ESS + PROPEL Mini implant (Treatment)

ESS alone (Control)

After frontal sinus surgery



Outcomes at 30 days



Narrowed frontal sinus opening

Case represents one patient experience from PROGRESS Study. Individual results may vary.

<sup>1</sup> Smith TL, Singh A, Luong A et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 126:2659–2664, 2016.



1555 Adams Drive  
Menlo Park, CA 94025  
650.641.2100  
info@intersectENT.com  
www.intersectENT.com

The PROPEL sinus implant is intended for use following ethmoid sinus surgery to maintain patency. PROPEL Mini is intended for use following ethmoid or frontal sinus surgery to maintain patency. The implants are intended for use in patients  $\geq 18$  years of age. Contraindications include patients with intolerance to mometasone furoate (MF) or a hypersensitivity to bioabsorbable polymers. Safety and effectiveness of the implant in pregnant or nursing females has not been studied. Risks may include pain/pressure, displacement of implant, and possible side effects of intranasal MF. The most common adverse events in clinical studies were sinusitis, headache, epistaxis and bronchitis. For complete prescribing information see IFU at [www.PROPELOPENS.com](http://www.PROPELOPENS.com). Rx only.

©2017 Intersect ENT, Inc. INTERSECT ENT and PROPEL are registered trademarks of Intersect ENT, Inc. in the United States and other countries. MPM 00329 Rev.A