



An Innovative Treatment Option for Patients with Recurrent Nasal Polyps

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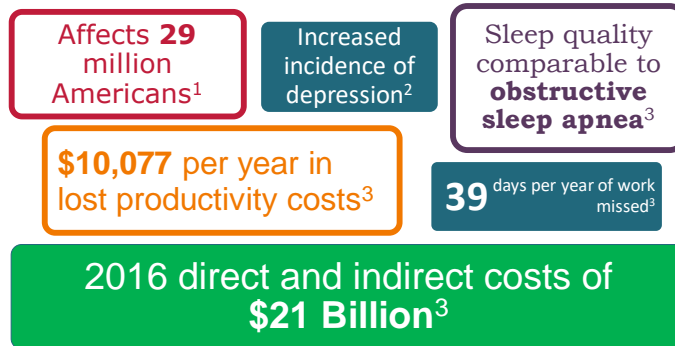
Burden of illness and management of Chronic Sinusitis with Nasal Polyps

Continuum of care and polyp recurrence

Clinical and health economic value of SINUVA™ for treatment of nasal polyps

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Societal Burden of Chronic Sinusitis (CS)



¹Summary health statistics tables for US adults: National Health Interview Survey, 2015. Table A-2. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/NHIS/SHS/2015_SHS_Table_A_2.pdf (accessed 2-22-2018).

²Campbell, et al: Depression symptoms and lost productivity in chronic rhinosinusitis, *Annals of Allergy, Asthma and Immunology*, March, 2017, Volume 118, Issue 3, 286-289.

³Deconde AS, Soler Z. CRS: Epidemiology and burden of disease; *American Journal of Rhinology and Allergy* 30, 134-139, 2016.

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Nasal Polyps

- Nasal polyps are soft, painless, noncancerous growths lining the nasal passages or sinuses.¹
- Caused by chronic inflammation due to asthma, recurring infection, allergies, drug sensitivity or certain immune disorders.¹
- Polyps lead to breathing problems, facial pain/headache, anosmia and frequent infections.¹
- **Nasal Polyps are present in ~31% of patients with Chronic Sinusitis.²**
- Patients with Chronic Sinusitis and nasal polyps may persist for a longer duration, be relatively recalcitrant to medical management, more frequently lead to surgical management and/or require more surgeries to address.³



¹Source: <https://www.mayoclinic.org/diseases-conditions/nasal-polyps/symptoms-causes/syc-20351888> (accessed 2-15-2018)

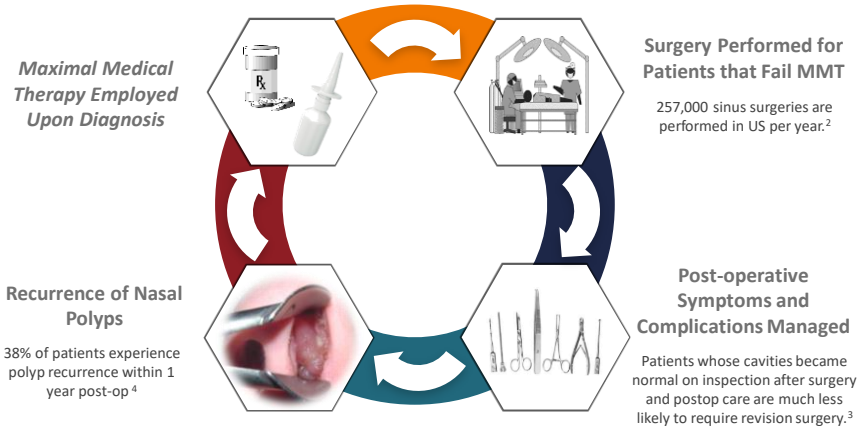
²Stein NR, et al. Revision rates and time to revision following endoscopic sinus surgery: A large database analysis. *Laryngoscope* 2017, Jul 8. doi: 10.1002/lary.26741.

³Hulse KE, et al. Pathogenesis of nasal polyposis. *Clin Exp Allergy*. 2015 February; 45(2): 328-346. doi:10.1111/cea.12472.

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Current Treatment Continuum

Symptom Resolution is Most Important to Patients, Public and Practitioners¹



¹ Orlandi et al; Cochrane Corner: Extracts from The Cochrane Library; Intranasal Steroids for CRS. Otolaryngology-Head and Neck Surgery 2017, Vol. 156(3):397-402.

² Bhattacharyya N. Ambulatory sinus and nasal surgery in the United States: demographics and perioperative outcomes. Laryngoscope 2010;120:635-638.

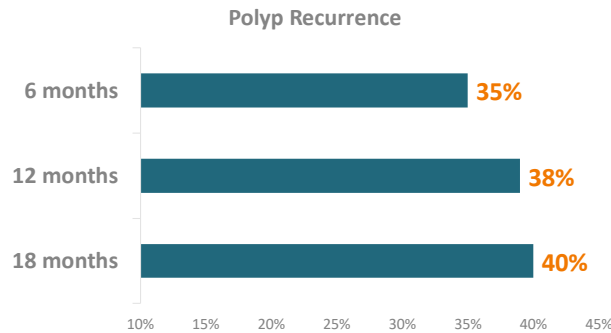
³ Kennedy DW, Wright ED, Goldberg AN. Objective and subjective outcomes in surgery for chronic sinusitis. Laryngoscope. 2000 Mar;110.

⁴ DeConde et al. Prevalence of Polyp Recurrence after ESS for CRSwNP; Laryngoscope, 127:550-555, 2017.

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Prevalence of Polyps Post Surgery

The rate of nasal polyp recurrence was documented in a study of 363 patients having undergone ESS with polypectomy. For patients in the study, 244 underwent graded postoperative endoscopies during the 18 month follow-up period.¹



¹ DeConde et al. Prevalence of Polyp Recurrence after ESS for CRSwNP; Laryngoscope, 127:550-555, 2017.

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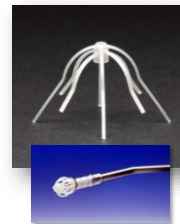


A NEW TREATMENT OPTION

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SINUVA™ (mometasone furoate) Sinus Implant

FDA Approval Type	Drug
FDA Approval Path	NDA
FDA Approval Date	December 8, 2017
Drug Component	Mometasone Furoate 1,350 µg
Drug Release Period	90 days



FDA INDICATION: The SINUVA Sinus Drug Implant is indicated for treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery.



Ethmoid Sinus
Pre-implant



Immediately
Following Insertion



6 Weeks
Post-treatment

The images shown represent a single patient outcome and may not be typical. The average nasal obstruction reduction score was -0.80 on a scale of 0 to 3 and the average polyp grade reduction score was -0.56 on a scale of 0 to 4 for patient in the experimental arm of the RESOLVE II study.¹

¹SINUVA- Prescribing information Dec 2017, <http://www.intersectent.com/wp-content/uploads/SINUVA-Prescribing-Information.pdf>

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Differentiation of Drug-Eluting Sinus Implants



PROPEL®

(Mometasone Furoate Sinus Implant, 370 µg)

FDA-Cleared as **DEVICE** via PMA in 2011

Clinical Application:

- Maintain sinus patency following surgery
- Reduce inflammation
- Decrease need for medical and surgical re-intervention following surgery

Clinical Setting:

- Following surgery in O.R. (HOPD or ASC)
- Adjunct surgical supply cost to facility



SINUVA

(Mometasone Furoate Sinus Implant, 1,350 µg)

FDA-Approved as a **DRUG** via NDA in 2017

Clinical Application:

- Treatment of nasal polyps in patients ≥ 18 years of age who have had ethmoid sinus surgery

Clinical Setting:

- Office/Clinic alternative for patients with recurrent disease eligible for revision surgery

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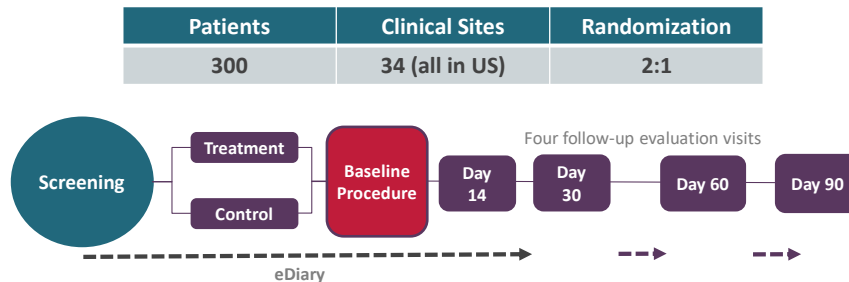
SINUVA Clinical Evidence Program

Pilot Study ¹	PK ²	RESOLVE ^{3,4*}	RESOLVE II ⁵
Non-Randomized Open Label Single Cohort (SINUVA Implant)	Non-Randomized Single Cohort Pharmacokinetic Study	Randomized 1:1 Blinded Controlled: Parallel Groups (SINUVA Implant vs. sham)	Randomized 2:1 Blinded Controlled: Parallel Groups (SINUVA Implant vs. sham)
n = 12 patients 4 sites Follow-up: 6 months	n = 5 patients 1 site 30 days	n = 100 patients 18 sites 6 months	n = 300 patients 34 sites 3 months

¹ Lavigne F, et al. Steroid-eluting sinus implant for in-office treatment of recurrent nasal polyposis: a prospective, multicenter study. *Int J Forum Allergy & Rhinol.* 2014;4(5):381-389.
² Ow R, Groppo E, et al. Steroid-eluting sinus implant for in-office treatment of recurrent polyposis: a pharmacokinetic study. *Int J Forum Allergy Rhinol.* 2014;4(10):816-822.
³ Han J, Forwitz K, Smith TL, et al. RESOLVE: a randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. *Int J Forum Allergy Rhinol.* 2014;4(11):891-870.
⁴ Forwitz, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes; *Int. Form Allergy Rhinol.* 2016; 6: 573-581. (Safety study)
⁵ Kern RC, et al. A phase 3 trial of mometasone furoate sinus implant for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol.* 2018 Jan 19. doi: 10.1002/alr.22084. PMID: 29350840. (Efficacy study)
 *Data on file, Intercept ENT. RESOLVE CSR R 28011. Version: 1.0. February 2016.

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RESOLVE II: Study Methods



- **Treatment group:** in-office bilateral implant placement in the ethmoid sinuses
- **Control group:** in-office bilateral sham procedure; patients blindfolded and ear-muffled
- **All patients** used mometasone furoate nasal spray (MFNS) once daily (200 mcg) through day 90 follow-up

Kern RC, et al. A phase 3 trial of mometasone furoate sinus implant for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Jan 19. doi: 10.1002/alr.22084. PMID: 29350840

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RESOLVE II: Baseline Characteristics

	Treatment	Control
Total no. of subjects	201	99
Male	63%	57%
Age (y)	51	48
Medical history:		
• Asthma	74%	62%
• Allergic rhinitis	77%	80%
• Aspirin exacerbated respiratory disease	15%	17%
ESS history:		
• Number of prior ESS		
• 1	41%	41%
• 2 or more	59%	59%
CRS symptoms despite ongoing use of INCS		
• Nasal obstruction/blockage	92%	91%
• Post-nasal discharge	91%	84%
• Altered sense of smell/taste	87%	90%
• Facial pain/pressure/fullness	38%	44%

Kern RC, et al. A phase 3 trial of mometasone furoate sinus implant for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Jan 19. doi: 10.1002/alr.22084. PMID: 29350840

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RESOLVE II: Statistically Significant Outcomes

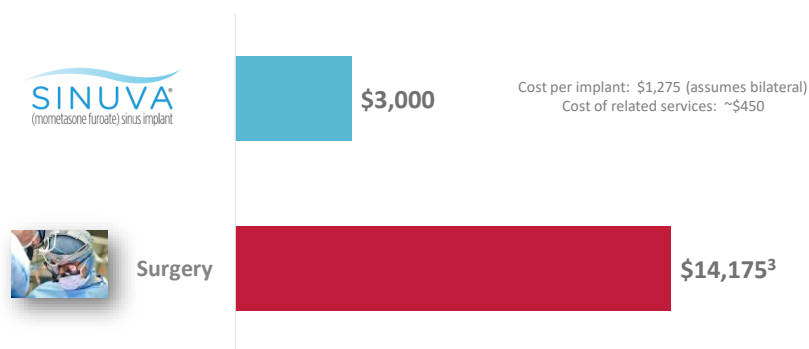
	Treatment (mean)	Control (mean)	Btw Group Difference	P value
<i>Co-Primary Efficacy Endpoints</i>				
Nasal obstruction/congestion score change (baseline to day 30, patient reported)	-0.80	-0.56	-0.23	0.0074
Bilateral polyp grade change (baseline to day 90 by independent blinded panel)	-0.56	-0.15	-0.35	0.0073
<i>Secondary Efficacy Endpoints</i>				
Patients still indicated for repeat sinus surgery at day 90	78/200 39%	62/98 63%		0.0004
Percent ethmoid sinus obstruction (baseline to day 90 by independent blinded panel)	-11.3	-1.9	-7.96	0.0007
Nasal obstruction/congestion score change (baseline to day 90, patient reported)	-0.93	-0.69	-0.27	0.0248
Decreased sense of smell score change (baseline to day 90, patient reported)	-1.20	-0.76	-0.46	0.0470

Kern RC, et al. A phase 3 trial of mometasone furoate sinus implant for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Jan 19. doi: 10.1002/alr.22084. PMID: 29350840

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Economic Value Proposition

The clinical benefits of SINUVA have been demonstrated as an alternative to surgery in patients with recurrent nasal polyps. In RESOLVE II, control pts had 2.7x higher risk of remaining indicated for revision surgery than treated patients at six months.¹



¹ Kern RC, et al. A phase 3 trial of mometasone furoate sinus implant for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Jan 19. doi: 10.1002/alr.22084. PMID: 29350840

² CMS National Average Payment for CPT 31231/31237. Assumes bilateral procedure with applicable payment reduction plus cost of two SINUVA implants @ \$1,275 WAC.

³ Tina D. Hunter, Adam S. DeConde & R. Peter Manes (2018): Disease-related expenditures and revision rates in chronic rhinosinusitis patients after endoscopic sinus surgery, Journal of Medical Economics, DOI: 10.1080/13696998.2018.1452748. (cost of revision surgery \$13,549 inflation adjusted to 2018)

MPM-00690 Rev. A

SINUVA Offers a Safe, Non-surgical Option to Patients With Recurrent Polyp Disease

Proposed Payor Coverage Criteria for SINUVA

- Diagnosis of Nasal Polyps
- Over age 18
- At least one prior ethmoid sinus surgery (*note: prior ethmoidectomy is required to accommodate implant size/shape*)
- Suboptimal response to appropriate medical therapy including:
 - INCS (intranasal corticosteroids) and/or oral steroids (unless ineligible or refused due to contraindications or intolerance)