Medtronic

SINUVA™ (mometasone furoate) sinus implant

Choose a different path

Nasal polyp reduction
following the SINUVA way

SINUVA sinus implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps, in patients ≥ 18 years of age who have had ethmoid sinus surgery.

Important safety information

Contraindications

Patients with a known hypersensitivity to mometasone furoate or any of the ingredients in SINUVA™ should not use SINUVA™.

Please see additional important safety information on the following page.

The road to symptom relief can be difficult

Nasal polyps develop by intrinsic mucosal inflammation that persists in the ethmoid sinuses[1,2]

Symptoms include:

Decreased or absent sense of smell

Nasal obstruction/ congestion

Runny nose/post-nasal discharge

Recommended treatment options for patients with nasal polyps include saline nasal rinses, topical intranasal, and oral corticosteroids[1]

Challenges of current recommendations

Topical intranasal corticosteroids	• ~60% of active drug in a metered dose of nasal steroid spray is removed by mucociliary clearance within 15 minutes[3] • Only 32.7% of patients use intranasal corticosteroids as directed[4]
Saline nasal rinses	Compared directly with topical nasal steroids, the benefits of saline irrigation alone are less pronounced[1]
Oral corticosteroids	Regardless of dosage and length of treatment, oral corticosteroids carry known safety concerns associated with chronic systemic exposure[5]

Important safety information (continued)

Warnings and precautions

Local effects: Monitor nasal mucosa adjacent to the SINUVA™ Sinus Implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Please see additional important safety information on the following page.


2 in 5
patients
may have polyp recurrence at 18 months[2]

Understanding the cyclical nature of nasal polyps

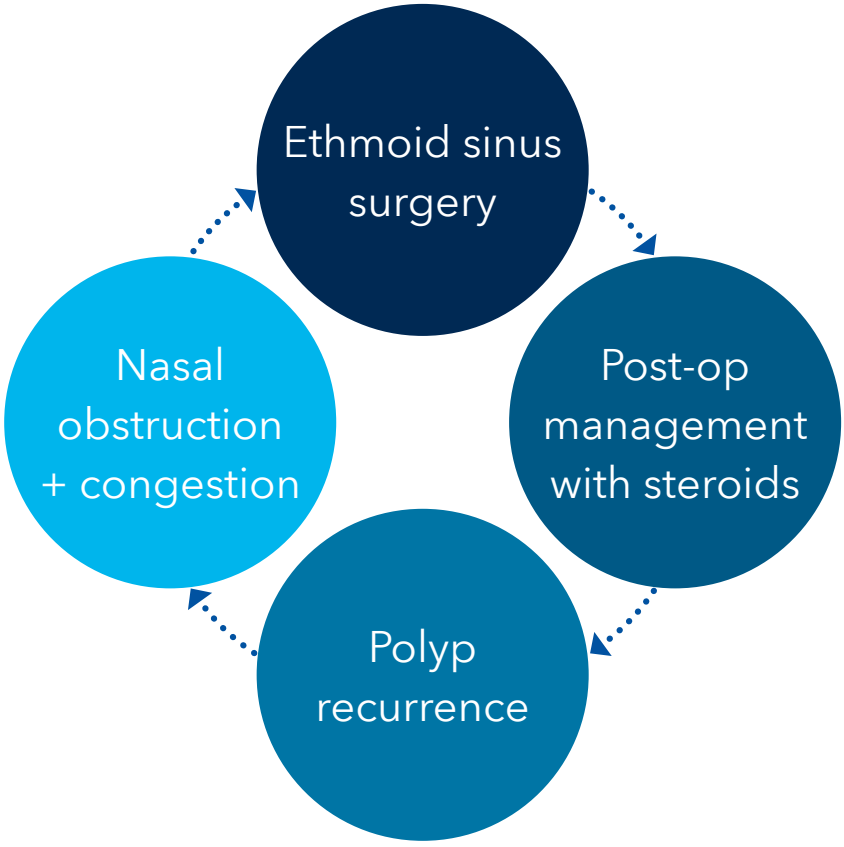
Patients who fail to achieve symptom relief with medication management may turn to endoscopic sinus surgery (ESS)

- Patients with nasal polyps require **revision ESS** more frequently than patients who do not have nasal polyps[6,7]
- More than **500,000 ESSs** are performed in the United States annually[8]
  - An estimated **60%** of patients who undergo ethmoid sinus surgery have symptoms reappear within one year of surgery[9]
  - Despite surgery, polyp recurrence was **35% at 6 months** and **40% at 18 months**[2]

Challenges of sinus surgery

- ESS for polyp removal is associated with higher blood loss than nonpolyp sinus surgery, with blood loss impairing visualization resulting in a riskier procedure[5]
- Surgical landmarks are often absent or distorted in revision ESS, making surgery more challenging and increasing risk for patients[5]

Despite the use of steroids and endoscopic sinus surgery, recurrence of nasal polyps is common due to the inflammatory nature of the disease, resulting in the need for repeat surgery in patients over time[6]



Choosing an alternative path to current nasal polyp treatment options with SINUVA™ (mometasone furoate) sinus implant

Which of your patients may benefit from SINUVA sinus implant?[10]

Patients ≥ 18 years of age who:

- Had previous ethmoid sinus surgery
- Have nasal polyps

Patients who meet these requirements and desire an alternative to revision sinus surgery to manage their symptoms may find relief with SINUVA sinus implant

Key benefits of SINUVA sinus implant

- SINUVA sinus implant is a novel implant with a **2-in-1** mechanism that offers patients with nasal polyps symptom relief via:
  - **Targeted** delivery of 1350 µg of mometasone furoate to the ethmoid nasal polyps[10]
  - **Self-expanding**, bioabsorbable design that softens over time[10]
- Continuous delivery of mometasone furoate over the course of 90 days[10]
- Localized drug delivery minimizes reliance on patient compliance
- Administered in a non-surgical, in-office procedure with local anesthesia[10]

Important safety information (continued)

Warnings and precautions (continued)

Ocular effects: Monitor patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts closely.

Please see additional important safety information on the following page.

Design of SINUVA sinus implant[10]

Width when crimped: 7.5 mm

Nominal uncrimped length of 20 mm

SINUVA™ (7.5 mm)

Dress shirt button (7 mm)

Why mometasone furoate?

Mometasone furoate offers high potency and low systemic bioavailability[11]

Lipophilicity
(absorption into tissue)

Glucocorticoid potency
(remains in the tissue)

Systemic bioavailability
(nominal systemic absorption)

SINUVA (mometasone furoate) sinus implant may create a path to improvement by demonstrating positive efficacy data

Co-primary efficacy outcomes[10,12,13*†‡]

In RESOLVE II (n=300), SINUVA™ patients experienced statistically significant reductions in bilateral polyp grade and nasal obstruction/congestion score

2.3x improvement in bilateral polyp grade

from baseline to day 90 compared to once-daily mometasone furoate nasal spray alone‡

Mean change (SD) for SINUVA implant –0.56 (1.06) vs. –0.15 (0.91) with control, mean group difference (95% CI) - 0.35 (-0.60, -0.09); (*P*=0.0073)

Significant improvement in nasal obstruction/congestion score

from baseline to day 30 compared to once-daily mometasone furoate nasal spray alone‡

Mean change (SD) for SINUVA implant –0.80 (0.73) vs. –0.56 (0.62) with control, mean group difference (95% CI) -0.23 (-0.39, -0.06); (*P*=0.0074)[1-3]

Important safety information (continued)

Warnings and precautions (continued)

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Immunosuppression: Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression: If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal..

SD, standard deviation.

*Patients in the SINUVA group also received once daily mometasone furoate nasal spray daily.[10]

†Co-primary endpoints: Change from baseline to day 90 in bilateral polyp grade, as determined by an independent panel on a scale of 0 (no visible nasal polyps) to 4 (nasal polyps completely obstructing nasal cavity). Change from baseline to day 30 in nasal obstruction/congestion score, as determined by patients on a scale of 0 (no symptoms) to 3 (severe symptoms).[10]

‡ Improvement calculated in post-hoc analysis as [(T-C)/C] *100 using values reported in the SINUVA prescribing information and Kern (2018).

Study design: The RESOLVE II study was a randomized, controlled, double-blind, multicenter study with 300 patients. Patients were ≥18 years of age with chronic sinusitis who had prior bilateral total ethmoidectomy, but were indicated for revision endoscopic surgery because they presented with moderate to severe nasal obstruction/congestion symptoms and recurrent bilateral sinus obstruction due to sinonasal polyposis despite the use of intranasal corticosteroid sprays and recent high dose steroids. 201 patients were randomized to the SINUVA implant treatment arm where they underwent bilateral placement of SINUVA implant in the ethmoid sinuses. 99 patients were randomized to the control arm where they received a sham procedure. Patients in both study arms received once-daily mometasone furoate nasal spray (200 µg) through day 90.[10,12]

Please see additional important safety information on the following page.

Secondary efficacy endpoints (baseline to day 90)[10,12,13§]

Reduced eligibility for repeat surgery

- SINUVA implant placement resulted in a **61% reduction in the proportion of patients still indicated for repeat ESS** vs. 37% in the mometasone furoate nasal-spray-only control arm at day 90. Odds ratio (95% CI) 2.69 (1.63, 4.44); (P=0.0004)

Delivered up to 90 days of sustained symptom relief

- Patients treated with SINUVA implant experienced sustained symptomatic **improvements in nasal obstruction/congestion** at day 90
- Mean change (SD) for SINUVA implant was –0.93 (0.80) vs –0.69 (0.79) with control, mean group difference (95% CI) -0.27 (-0.48, -0.07); (P=0.0248)

Significantly reduced sinus obstruction

- Patients treated with SINUVA implant had a significantly greater **decrease in percent ethmoid sinus obstruction** at day 90
- Mean change (SD) for SINUVA implant was –11.3 (18.1) vs –1.9 (14.4) with control, mean group difference (95% CI) –7.96 (–12.10, –3.83); (P=0.0007)

Improved patients' sense of smell

- Patients treated with SINUVA implant experienced a **significant improvement in their self-reported decreased sense of smell score** at day 90 on a six-point Likert scale
- Mean change (SD) for SINUVA implant was –1.20 (1.66) vs. –0.76 (1.60) with control, mean group difference (95% CI) –0.46 (–0.85 –0.06); (P=0.0470)

Patients treated with SINUVA™ did not experience a significant improvement in their self-reported facial pain/pressure score. The mean change (SD) for SINUVA implant was –0.77 (1.21) vs. –0.90 (1.27) with control (P=0.9130)

SD, standard deviation.

§Secondary endpoints: Proportion of patients still indicated for repeat ESS at day 90 despite ongoing intranasal steroid use based on clinical investigator assessment using study-specific criteria. Change from baseline to day 90 in instantaneous nasal obstruction/congestion score (daily diary), as determined by patients on a scale of 0 (no symptoms) to 3 (severe symptoms). Change in percent ethmoid sinus obstruction at day 90, as determined by the independent, blinded panel on a 100 mm visual analogue scale (VAS). Decreased sense of smell and facial pain/pressure score change from baseline to day 90, as determined by patients on a six point Likert scale of 0 (absent) to 5 (very severe). P-values for secondary endpoints were prespecified and adjusted for multiplicity.[12]

SINUVA™ (mometasone furoate) sinus implant safety data

Adverse reactions at 90 days with > 1% incidence rate and more common in treatment than the control group in combined data from the RESOLVE and RESOLVE II studies[10]

Adverse reactions	SINUVA™ (n=254) n (%)	Control (Mometasone furoate nasal spray) (n=146) n (%)
Asthma	12 (4.7)	6 (4.1)
Headache	9 (3.5)	5 (3.4)
Epistaxis	6 (2.4)	2 (1.4)
Presyncope	6 (2.4)	3 (2.1)
Bronchitis	5 (2.0)	2 (1.4)
Otitis media	5 (2.0)	2 (1.4)
Nasopharyngitis	3 (1.2)	1 (0.7)

In clinical trials, SINUVA sinus implant demonstrated similar local effects and hypersensitivity reactions compared to once daily mometasone furoate nasal spray alone, with a low incidence of serious adverse events[10,12]

- Patients on SINUVA sinus implant did not experience any significant increase in intraocular pressure, glaucoma, or any form of cataract[10]

Please see additional important safety information on the following page.

Ordering + coding SINUVA sinus implant

Ordering

SINUVA implants can be obtained through two accessible avenues:

1. **Specialty distributor:** providers can purchase SINUVA implants directly from a distributor. Benefits verification and prior authorization from the payer is recommended prior to implanting a patient.
2. **Specialty pharmacies:** In some cases SINUVA implants can be filled under the pharmacy benefit by a select specialty pharmacy and delivered directly to the provider. Verifying the patient's benefits will establish the path to fulfillment.

Coding

ICD-10 code	Descriptor
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified

HCPCS codes	Billable units	Descriptor
J7402	1 unit for every 10 mcg = 135 billing units	Mometasone furoate sinus implant (sinuva), 10 micrograms

NDC number	Descriptor
10599000301	SINUVA™ (mometasone furoate) 1350mcg

If SINUVA sinus implant is distributed via Specialty Pharmacy, providers should only bill the appropriate CPT procedural code for placing SINUVA implants. Codes listed above are recommendations and do not guarantee payment or reimbursement.

Visit SINUVA.com/hcp for more information regarding ordering + coding.

INDICATION

SINUVA™ (mometasone furoate) sinus implant is a corticosteroid-eluting (mometasone furoate) implant indicated for the treatment of nasal polyps, in patients ≥ 18 years of age who have had ethmoid sinus surgery.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate and any of the ingredients of the SINUVA sinus implant should not use SINUVA implants.

WARNINGS AND PRECAUTIONS

Local Effects: Monitor nasal mucosa adjacent to the SINUVA sinus implant for any signs of bleeding (epistaxis), irritation, infection, or perforation. Avoid use in patients with nasal ulcers or trauma.

Ocular Effects: Monitor patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts closely.

Hypersensitivity Reactions: Hypersensitivity reactions, including rash, pruritus, and angioedema have been reported with the use of corticosteroids.

Immunosuppression: Persons who are using drugs that suppress the immune system are more susceptible to infections than healthy individuals. Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract; untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

Hypercorticism and Adrenal Suppression: If corticosteroid effects such as hypercorticism and adrenal suppression appear in patients, consider sinus implant removal.

ADVERSE REACTIONS

The most common adverse reactions observed (> 1% of subjects and that occurred more frequently in the treatment group compared to control) in clinical studies were asthma, headache, epistaxis, presyncope, bronchitis, otitis media, and nasopharyngitis.

POSTMARKETING EXPERIENCE

The following adverse reactions have been identified during post-approval use of the SINUVA sinus implant. These events include implant migration, lack of efficacy, nasal pain, headache, epistaxis.

Rx only. Please see accompanying Full Prescribing information for SINUVA sinus implant or at SINUVA.com/PI.

References

1. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg.* 2015;152(2 Suppl):S1-S39.
2. DeConde AS, Mace JC, Levy JM, et al. Prevalence of polyp recurrence after endoscopic sinus surgery for chronic rhinosinusitis with nasal polyposis. *Laryngoscope.* 2017;127(3):550-555.
3. Shah SA, Berger RL, McDermott J, et al. Regional deposition of mometasone furoate nasal spray suspension in humans. *Allergy Asthma Proc.* 2015;36(1):48-57.
4. Bender BG. Motivating patient adherence to allergic rhinitis treatments. *Curr Allergy Asthma Rep.* 2015;15(3):10.
5. Campbell RG. Risks and management of long-term corticosteroid use in chronic rhinosinusitis. *Curr Opin Otolaryngol Head Neck Surg.* 2018;26(1):1-7.
6. Hull BP, Chandra RK. Refractory chronic rhinosinusitis with nasal polyposis. *Otolaryngol Clin North Am.* 2017;50(1):61-81.
7. Stein NR, Jafari A, DeConde AS. Revision rates and time to revision following endoscopic sinus surgery: A large database analysis. *Laryngoscope.* 2018;128(1):31-36.
8. Data on File. MRG 2012 US Markets for ENT and Bronchoscopy.
9. Wynn R, Har-El G. Recurrence rates after endoscopic sinus surgery for massive sinus polyposis. *Laryngoscope.* 2004;114(5):811-813.
10. SINUVA™ [Prescribing Information]. Menlo Park, CA: Intersect ENT; 2017.
11. Sastre J, Mosges R. Local and systemic safety of intranasal corticosteroids. *J Investig Allergol.* 2012;22(1):1-12.
12. Kern RC, Stolovitzky JP, Silvers SL, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. *Int Forum Allergy Rhinol.* 2018;8(4):471-481.
13. Data on file, Intersect ENT, Inc. CR-00014; Supplemental Statistical Analyses Rev 1.0 January 17, 2018.

For more information, visit **SINUVA.com/hcp**.

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