



*For adults with nasal polyps who have
had previous ethmoid sinus surgery*

*Innovation that helps
you breathe easier*

INDICATION

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

Please see accompanying Full Prescribing Information for Important Safety Information about SINUVA.

SINUVA[®]
(mometasone furoate) sinus implant

If you're suffering from nasal polyps, you are not alone.

Studies, including a survey by the National Center for Health Statistics, have shown that up to 10% of all Americans suffer from chronic sinusitis, with or without nasal polyps.

Symptoms of this condition include nasal discharge, loss of smell, facial pain, and persistent nasal obstruction, which can make it difficult to breathe. Symptoms are often treated with **intranasal steroid sprays, saline rinses, and oral steroids.**

To help address significant cases of chronic sinusitis, more than 500,000 endoscopic sinus surgeries (ESS) are performed in the United States annually.

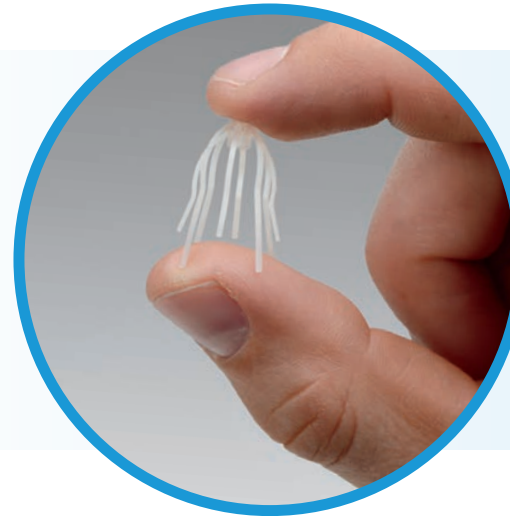
“More than 500,000 endoscopic sinus surgeries are performed in the US annually.”

Unfortunately, these procedures may not prevent symptom recurrence.

About 60% of all people who had ESS will return to their doctors with symptoms of chronic sinusitis within a year.

And **one in four will return for surgery** at some point, many of them within a year of the first procedure.

The recurrence of nasal polyps after sinus surgery necessitates additional therapy options that can help patients.



**There's another option.
The SINUVA™ Sinus Implant.**

SINUVA was designed to treat nasal polyps and is an alternative to surgery and other treatment options **for adults who have already had ethmoid sinus surgery.**

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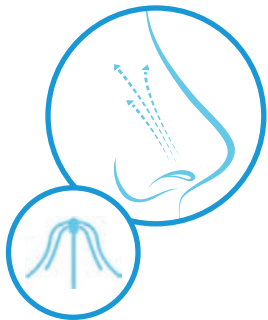
What is SINUVA?

The SINUVA Sinus Implant is an innovative technology that reduces polyps and the sensation of nasal congestion and obstruction with a 2-in-1 approach:

2-in-1

Designed to open in the sinus cavity

Delivers anti-inflammatory medicine to treat nasal polyps



- SINUVA is delivered into the sinus cavity through the nasal opening during a routine office visit
- A doctor will use topical and/or local anesthesia to numb your nose and sinuses
- SINUVA usually cannot be felt once it's in place
- SINUVA will be removed at 90 days or earlier at your doctor's discretion

Did you know your nasal spray has a hard time reaching your sinuses?

Because of nasal polyp obstruction, the medicine in the spray doesn't always reach its target. That's why one of the benefits of SINUVA is that it reduces the blockage in the nasal passage which may allow the spray to reach the area where it's needed most.



According to Kern et al, 2017: IFAR.

Ask your doctor if SINUVA is right for you.

How well does SINUVA work?

SINUVA is proven to shrink nasal polyps and reduce nasal obstruction and congestion. As it stays in the sinus and continues to release medicine, SINUVA offers sustained symptom relief for up to 90 days.

In addition, SINUVA is proven to significantly reduce sinus obstruction, improve a patient's sense of smell, and reduce their need for surgery.



SINUVA was studied in a clinical trial with 201 patients who received SINUVA and 99 patients who underwent a procedure as a placebo. All patients in the study were diagnosed with chronic sinusitis who had already undergone sinus surgery, but were candidates for revision surgery. Whether they received SINUVA or not, all patients were required to use a nasal spray daily that contained steroids.

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Is SINUVA safe?

Because SINUVA is placed directly amongst the nasal polyps, it's able to provide sustained symptom relief with a low rate of side effects.

The safety of SINUVA was established in 400 patients in 2 clinical trials

- The most common side effects were asthma, headache, and nose bleed. This is how the patients who received SINUVA compared to those in the control group:

	Asthma	Headache	Nose Bleed
Control	4.1%	3.4%	1.4%
SINUVA	4.7%	3.5%	2.4%

See the accompanying Full Prescribing Information for a complete list of side effects reported in the clinical trial and since SINUVA's approval.



As with all endoscopic sinus procedures, there are risks associated with the insertion and removal of the SINUVA Sinus Implant.

- The risks from SINUVA are similar to those associated with other endoscopic sinus procedures, such as nose bleed, injuries to blood vessels, and bacterial infection
 - SINUVA has not been studied in people with cystic fibrosis, acute bacterial infections, or invasive fungal sinusitis
 - SINUVA is not for people with hypersensitivity to corticosteroids or those with nasal ulcers or trauma

Contact a doctor immediately if you experience:

- Excessive nasal bleeding or symptoms of infection, such as excessive pain or discomfort, persistent headache, or increased sinus discharge
- Symptoms suggesting that the implant has moved, such as irritation or a choking sensation in the back of the throat

Hypersensitivity reactions, including rashes, itching, and hives, have been reported with use of the medicine in SINUVA. Remove the SINUVA sinus implant if such reactions occur.

Close monitoring is recommended for patients with a change of vision or a history of increased intraocular pressure, glaucoma, and/or cataracts.

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Frequently Asked Questions

How do I get SINUVA?

SINUVA is prescribed and placed by your doctor if appropriate. Ask your doctor if SINUVA is right for you.

How is SINUVA implanted in my sinus cavity?

SINUVA is placed in your doctor's office, using local anesthesia. After numbing your nose, your doctor will introduce the SINUVA implant into your nostril on the end of a Delivery System, and place the implant within your sinus.

How long does the SINUVA procedure take?

In SINUVA clinical studies, the typical procedure took 30-40 minutes. This includes 10-30 minutes to numb your nose and ~5-10 minutes to place the SINUVA Implants.

How does SINUVA work to reduce nasal polyps?

SINUVA is implanted in your sinus cavity next to the nasal polyps to provide local delivery of a drug called mometasone furoate (a type of steroid). The Implant has been shown to be effective in reducing nasal obstruction and congestion, and shrinking polyps.

How much medicine is in each implant?

Each SINUVA Sinus Implant contains 1350 mcg of mometasone furoate.

Should I continue to use saline irrigations or nasal sprays after the SINUVA procedure?

Yes, you are encouraged to use both saline irrigations and nasal sprays as needed.

What happens to the implant while it's in my body?

The implant is designed to release medicine over the course of 90 days. The implant gradually softens over time while it is in your sinus.

Will the implant be removed by a doctor?

SINUVA is designed to deliver the drug over the course of 90 days and will be removed at that time or earlier at your doctor's discretion.

Can I sneeze out the implant?

As the implant softens and polyps decrease, the implant may, in part or in whole, be expelled out of the nose on its own or with actions such as sneezing or forceful nose-blowing.

Is SINUVA covered by insurance?

Many insurance policies will cover SINUVA. It is important to check with your insurance provider to ensure that your treatment plan is covered under their policy.

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IMPORTANT SAFETY INFORMATION

Who should not use SINUVA?

Do not use SINUVA if you are allergic to mometasone furoate or any ingredients of the implant.

What should I tell my doctor before receiving SINUVA?

Before you receive SINUVA, tell your doctor about all medical conditions you have including nasal/sinus problems (such as nasal ulcers or trauma), eye problems (such as glaucoma or cataracts), or any untreated fungal, bacterial, or viral infections.

What are the possible side effects of SINUVA?

Serious side effects of SINUVA can include:

- **Local reactions** including nosebleed and injury to nerves or blood vessels in the nose/sinus.
- **Serious allergic reactions** have happened in patients using mometasone furoate including rash, itching or swelling of the lips, face, tongue, and throat, and breathing problems. Call your doctor right away if you have any of these reactions.
- **Weakened immune system** that may increase your risk of infections. Avoid contact with people who have contagious diseases such as chickenpox or measles. Call your doctor right away if you have been near someone with chickenpox or measles.
- **Adrenal insufficiency** is a condition in which the adrenal glands do not make enough steroid hormones and can cause tiredness, weakness, nausea and vomiting and low blood pressure. Talk to your doctor if steroid effects such as Cushing Syndrome and adrenal suppression appear.

The most common side effects of SINUVA in clinical studies were bronchitis, cold symptoms, middle ear infections, headache, lightheadedness or dizziness, asthma, and nosebleeds. 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, and nosebleeds.

Tell your doctor if you have any side effects that bother you or don't go away.

Risks related with the insertion and removal of SINUVA are similar to other endoscopic sinus procedures.

SINUVA is made from materials designed to soften over time and may fall out of the nose on its own as polyps decrease or if you sneeze or blow your nose forcefully. The implant will be removed 90 days after placement or earlier at your doctor's discretion.

Contact your doctor immediately if you have any changes in vision, excessive nasal bleeding, symptoms of infection or symptoms suggesting that the implant has moved, such as irritation or a choking sensation in the back of the throat.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For important risk and use information, please see accompanying Full Prescribing Information for SINUVA or at SINUVA.com/PI

