



*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  $\geq 18$  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

*Designed to Deliver.*

# 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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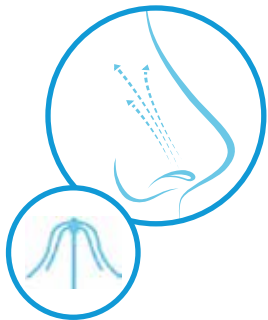
# What is SINUVA™?

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 can 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.



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 may 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**

If you have a known hypersensitivity to the mometasone furoate drug or any of the ingredients in SINUVA, do not use SINUVA. Hypersensitivity reactions, including rash, itch, and swelling have been reported with use of steroids. If steroid effects such as Cushing Syndrome and adrenal suppression appear, consult your healthcare professional.

SINUVA is made from bioabsorbable polymers designed to soften over time. As the implant softens and polyps decrease, the implant may be expelled out of the nose on its own or with actions such as sneezing or forceful nose blowing. The implant can be removed 90 days after placement or earlier at the physician's discretion. Repeat administration of SINUVA has not been studied.

As with other endoscopic sinus procedures, there are risks associated with the insertion or removal of SINUVA. SINUVA should be inserted by physicians trained in otolaryngology. Discuss risks related to insertion or removal of SINUVA with your healthcare professional.

Your healthcare professional will monitor the nasal tissue adjacent to the SINUVA Sinus Implant for any signs of bleeding, irritation, infection, or perforation. SINUVA should not be used in patients with nasal ulcers or trauma.

The most common adverse reactions observed in clinical studies were bronchitis, upper respiratory or middle ear infection, headache, lightheadedness, asthma, and nose bleed.

If you experience 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, immediately contact a healthcare professional.

Close monitoring is recommended if you have a change of vision or a history of increased intraocular pressure, glaucoma and/or cataracts.

You may report side effects to your physician or to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). You may also report side effects to Intersect ENT at 1-866-531-6004.

RX Only. For important risk and use information about SINUVA, please see Full Prescribing Information available at [www.SINUVA.com](http://www.SINUVA.com)



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1555 Adams Drive, Menlo Park, CA 94025

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