Chronic Sinusitis

One in eight adults is affected by chronic sinusitis each year, making it one of the most common health conditions in the U.S.\(^1\)

The sinuses are air-filled cavities located within the bones around the nose and eyes that allow for airflow and drainage. In chronic sinusitis, diseased sinus linings become swollen (inflamed), preventing natural drainage, leading to chronic infections and nasal blockage.

Nasal polyps are seen in severe cases of chronic sinusitis as a result of increased swelling (inflammation) of the sinus lining. Small nasal polyps may not cause discomfort. However, larger growths or groups of nasal polyps often block your nasal passages leading to breathing problems, lost sense of smell, and frequent infections.\(^2\)

Learn about the [treatment options.](#)

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frequently asked questions

Below are answers to some commonly asked questions about the RESOLVE II Study.

Q: Who can participate in this study?
Q: Has this sinus product been studied in humans before?
Q: What are possible risks and discomforts?
Q: I am interested in hearing more. What is the next step?
Q: What will I have to do if I decide to participate in the study?
Q: What are the benefits of participating in the study?
Q: Will I be paid if I take part in this study?
Q: Can I voluntarily withdraw from the study?
Q: Who will pay for the procedure?
Q: **Who can participate in this study?**

A: If your symptoms of nasal blockage have returned after sinus surgery, you might be eligible to participate in this study. To determine the intensity of your symptoms, you will be asked to complete a daily diary via phone for 14 days. For more information, please click the “Eligible Patients” tab above or contact a clinical study site near you.

The study is designed to enroll 300 patients altogether in this study at up to 45 sites across the United States. Participants will be in the studied for 3 months after the product placement.

Q: **Has this sinus product been studied in humans before?**

A: The investigational, steroid-eluting product has been evaluated in 3 studies with 117 patients. The purpose of the RESOLVE II Study is to test the product in a larger group of patients.

Q: **What are possible risks and discomforts?**

A: Like all clinical research studies, there are some risks associated with the RESOLVE II Study. Please contact the clinical study site near you to learn more about the possible risks and discomforts.

Q: **I am interested in hearing more. What is the next step?**

A: To get connected with the local RESOLVE II Study center in your area, the next step is taking the pre-screening questionnaire. The questionnaire will help determine if you meet some of the main criteria for the study. If the pre-screening questionnaire indicates you qualify, you will be given the option to have your contact information sent directly to the local RESOLVE II Study center in your area. Someone from your local study center will then contact you within a couple of
days to tell you more about the study, and help you decide whether you would like to participate. Please [click here](#) to find out how to take the pre-screening questionnaire.

**Q:** What will I have to do if I decide to participate in the study?

**A:** After you agree to participate in the study and sign the informed consent form, you will undergo the following screening procedures to determine if you are eligible for the study:

- Interview by the study doctor
- Complete symptom questionnaires
- Complete a daily diary for 14 days
- Undergo an endoscopy to determine the current status of your sinuses
- Give urine for a pregnancy test, if you are female of child bearing age

**Q:** What are the benefits of participating in the study?

**A:** As participants in this study, the patients are partners in research and play an important role in advancing the treatment choices for chronic sinusitis.

By taking part in the RESOLVE II study, you can try this new chronic sinusitis treatment, which may or may not be better than the treatment options that already exist to help your condition. While no benefit is guaranteed, it is possible that your sinus condition may get better. While it is also possible that your condition may remain unchanged or get worse, we hope the information learned from this research study will benefit other individuals with recurrent sinus obstruction in the future. The participants in this study will help the researchers to learn more on the treatment options for chronic sinus disease.
Q: Will I be paid if I take part in this research study?
A: Patients will be compensated for their time and travel associated with their participation in the study.

Q: Can I voluntarily withdraw from the study?
A: Taking part in this study is voluntary. You can withdraw your consent or discontinue participation in this study at any time. Your decision to leave the study will not cause any penalty or loss of benefits to which you are entitled.

Q: Who will pay for the procedure?
A: All study related costs will be covered by the Sponsor of the study. The company responsible for this study is Intersect ENT, headquartered in Menlo Park, California. To learn more about the company, please visit www.intersectent.com
glossary of terms

We understand that the decision to participate in a clinical study requires you to consider a number of factors. The scientific language used is often hard to understand. This glossary is aimed to define some of these scientific terms.

**Blinded**: This study design is often used in studies which compare two different treatments. Blinding prevents the participant from knowing certain information that might lead to a bias on their part.

**FDA**: The Food and Drug Administration (FDA) is an agency of the United States Department of Health and Human Services. The FDA is responsible for protecting public health through the regulation and supervision of health products like pharmaceutical drugs, vaccines, medical devices and veterinary products.

**Investigational**: The sinus product being studied in RESOLVE II is considered investigational
because it has not been approved for commercialization by the United States Food and Drug Administration (FDA). The RESOLVE II Study is evaluating its safety and effectiveness. The data collected during the RESOLVE II Study will be used to obtain the FDA approval for this product.

**IRB:** An Institutional Review Board (IRB), also known as an independent ethics committee or ethical review board, is a committee that approves, monitors, and reviews biomedical and behavioral research involving humans. The purpose of an IRB review is to ensure that appropriate steps are taken to protect the rights and health of patients in a research study.

**Multi-Center:** A multi-center trial is a study which is conducted at more than one site of patient care. For example, the RESOLVE II Study will enroll patients at 45 US centers. Multiple centers of study ensure that the study enrolls participants from various geographic locations and are represented by different ethnic groups and gender.

**Control Group:** A control group is a group of patients in a clinical trial that does not receive the treatment being studied, so that comparisons can be made between the two groups. For example, in the RESOLVE II Study, the participants in the control group will not receive the new treatment option, but will take an FDA-approved topical steroid spray and will undergo the same level of care as the participants who receive the new treatment option. The results of the control group are compared to the results of the treatment group, and that data is used to decide if the new treatment option is effective in treating the disease. Without the control group, there would be no way to compare the new treatment option to the current treatment options.

**Prospective:** A prospective study observes the participants over a pre-defined time of period set at the start of the study. Various results are collected at regular time intervals to measure the effectiveness of the investigational treatment.

**Randomized:** A randomized study design randomly assigns participants in the study to either the
control or the treatment group. A randomized design is used to prevent bias on the parts of the participants and the doctors administering the investigational treatment.
still suffer from nasal blockage after sinus surgery?

if so, you may qualify for the RESOLVE II Study.

RESOLVE II is a study to determine whether an investigational, dissolvable, steroid-releasing sinus product can improve chronic sinusitis symptoms in patients who had sinus surgery but continue to experience symptoms.
Caution: New Drug — Limited by Federal (or United States) law to investigational use.
list of study centers

Below is the current list of locations for the RESOLVE II Study.

**Iowa**

**Iowa ENT Center**
105 Valley West Drive, West Des Moines, IA 50265
Contact: Kristi Chapman
Tel: 1-855-974-6879 (855-9-SINUS-9)
Email: kristi@resolvesinusstudy.com
Principal investigator: Simon Wright, MD

**Kentucky**

**Advanced ENT and Allergy**
4004 Dupont Circle, Suite 220, Louisville, KY 40207
Contact: Kathleen Sheeley, RRT, CCRC
Tel: 1-855-974-6879 (855-9-SINUS-9)
New Jersey

Summit Medical Group
Bensley Pavilion, One Diamond Hill Road, Berkley Heights, NJ 07922
Contact: Kelly M. Ritter, RN, CCRC
Tel: 1-855-974-6879 (855-9-SINUS-9)
Email: kelly@resolvesinusstudy.com
Principal Investigator: Andrew Gould, MD

New York

Madison ENT
161 Madison Ave, Suite 11W, New York, NY 10016
Contact: Christine Chung
Tel: 1-855-974-6879 (855-9-SINUS-9)
Email: christine@resolvesinusstudy.com
Principal investigator: Stacey Silvers, MD

Utah

Intermountain/ENT Center of UT
22 South 900 East, Salt Lake City, UT 84102
Contact: Holly Featherstone, CCRC
Tel: 1-855-974-6879 (855-9-SINUS-9)
Email: holly@resolvesinusstudy.com
Principal investigator: Steven K. Miller, MD

Virginia

Reston ENT
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

How did you first learn about the RESOLVE II Study?

Select one...

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Please enter your zip code so that we can find the nearest RESOLVE II Study location:

Submit
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Based on your zip code, the following RESOLVE II Study location(s) have been found in your area. Please select the location that is most convenient for you:

- Intersect Demo Site - Menlo Park, CA - 10.6 mi.

[Continue]
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

If you qualify and choose to join the RESOLVE II Study, would you be able to travel to this location for your treatment, and 4 follow-up visits over a 4-month period?

- Yes
- No

[Continue]
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

What is your age?

- < 18
- 18 - 29
- 30 - 39
- 40 - 49
- 50 - 59
- 60 - 69
- 70 - 79
- 80 or older

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Have you ever had sinus surgery?

- Yes
- No

[Continue]
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

When did you have your most recent sinus surgery?

- Within the past 3 months
- Within the past 4 - 12 months
- Within the past 1 - 3 years
- Within the past 3 - 5 years
- More than 5 years ago

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Have you been told by a doctor that you have chronic sinusitis?

- [ ] Yes
- [ ] No
- [ ] Not sure

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Have you been told by a doctor that you have nasal polyps or sinus polyps?

- Yes
- No
- Not sure

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Are you currently experiencing any of the following symptoms? (Please check all that apply)

- [ ] Nasal obstruction/blockage
- [ ] Post-nasal discharge
- [ ] Thick nasal discharge
- [ ] Facial pain, pressure, or fullness
- [ ] Decreased sense of smell
- [ ] None of these

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Within the past 1 year, have you taken steroids (nasal or oral) to treat your sinus condition?

- Yes
- No
- Not sure

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Do you have any medical conditions (other than your sinus condition) that require you to take oral steroid medications on a regular basis, such as COPD or asthma?

- Yes
- No

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Have you been diagnosed with glaucoma?

- Yes
- No

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Do you have diabetes that requires you to take insulin?

- Yes
- No

[Continue]
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Are you currently participating in any clinical research study?

- [ ] Yes
- [ ] No

Continue
pre-screening questionnaire

The questionnaire will take about 4 or 5 minutes to complete.

Thank you. Your responses have met the preliminary criteria for the study.

If you're still interested in participating in the study, please enter your contact information below. Your information will be added to a database and someone from your local RESOLVE II Study center will then contact you within the next few days to tell you more about the study, and answer any questions you might have.

By speaking with your local study site, you are not under any obligation to join the study. Also, only your local study site can determine whether or not you may be eligible to join the study.

Please note: your contact information will only be shared with your local RESOLVE II Study site so that they can follow up with you directly to discuss the study—with it will not be used for any other purpose.

Your Name*
First Name
M Last Name

Address*
Street
City State/Province ZIP Code

Phone*

Email Address

* Required Field

Review
in-office procedure

The procedure will be performed in the ENT doctor's office through the patient's nostrils. The patient will be awake throughout the procedure.

Prior to the procedure, the physician will perform a nasal examination using an endoscope. To ensure patient comfort, the doctor will numb the nose and sinuses using nasal spray. In some circumstances the doctor may choose to inject the nasal passage with a mild anesthetic. The procedure requires no incisions and will take only a few minutes. The total appointment time will be approximately 60 minutes.

The patient may return to work the same day. The recovery from the procedure is expected to be similar to a dentist’s visit, with some numbness around the nose and face immediately following the procedure. Minor nose bleeding might also be observed for a few minutes after the procedure.

Learn more about the sinus product.
new treatment option

An investigational, dissolvable, steroid-releasing sinus product was developed as a new potential treatment option for chronic sinusitis with nasal polyps. This umbrella-shaped product is approximately 1 inch long and is coated with a small amount of steroid to reduce inflammation. The steroid is mometasone furoate, the same drug contained in the nasal spray Nasonex. Nasonex is approved by the U.S. Food and Drug Administration (FDA) to treat nasal polyps.

The sinus product is placed in the doctor’s office.

Learn more about the procedure.

a new investigational treatment alternative to oral steroid therapy or revision sinus surgery for chronic
Caution: Investigational drug product. Limited by federal law to investigational use only. Not approved for sale in the U.S.
the RESOLVE II Study locations

Click on a map pin to display the contact information for that RESOLVE II Study site. Or click here to see a list of the study locations.
Right now, doctors throughout the U.S. are conducting the RESOLVE II clinical study.

To see if you might qualify for the RESOLVE II Study, please contact the center near you to speak with a study specialist.

**pre-screening questionnaire**

The pre-screening questionnaire is the first step towards participating in the RESOLVE II Study. The questionnaire will help determine if you meet the criteria for participating in the study. If you meet the pre-screening criteria, you will be given the option to submit your contact information to the RESOLVE II Study center in your area. Someone from your local study center will then contact you within a couple of days to tell you more about the study, and answer any questions you might have. Only your local study center can determine if you are eligible to join the study.
Click the link below to take the pre-screening questionnaire.

Please note that completing the pre-screening questionnaire does NOT obligate you to participate in the study. Rather, the pre-screening questionnaire simply helps determine if you might be a potential candidate for the study, so that you can be connected to the local RESOLVE II Study center in your area to learn more.
nasal polyps treatment options

Medications like oral steroids can often shrink nasal polyps, but surgery is often needed to remove them. During surgery, the Ear, Nose and Throat (ENT) surgeon enters the sinuses through the nostrils to open blocked sinus pathways, clean out infection and remove the polyps. Opening the inflamed sinus pathways allows the sinuses to drain better and improves air flow.

Even after successful treatment, nasal polyps frequently return. In such situations, the only available options to treat your symptoms are oral steroids and additional sinus surgery.

The sinus product being studied in the RESOLVE II Study is a non-invasive investigational treatment option. The product is placed in the doctor's office. It has the potential to improve the patient's symptoms by clearing the nasal blockage and delivering a small dose of steroids directly to the sinus lining.

Click here to learn more about the sinus product.
who can participate?

Clinical research is vital to developing new therapies to treat chronic sinusitis. The researchers are committed to making participants' experiences as comfortable and satisfying as possible.

Patients suffering from chronic sinusitis who have undergone sinus surgery can participate in this study. As participants, the patients are partners in research and play an important role in advancing the treatment choices for chronic sinusitis.

eligibility criteria

Study participants must meet the following initial requirements in order to be further evaluated for participation:

- Be 18 years of age or older
- Have had sinus surgery on both ethmoid sinuses
- Have not had sinus surgery in the past 3 months
- Have continuing symptoms of chronic sinusitis such as congestion, runny nose, facial
pain/pressure, or altered smell and/or taste

- Have current medical treatment for continuing symptoms that is not working effectively

To see if you might qualify, and to be connected with the RESOLVE II Study center in your area, click here.
RESOLVE II Study

the RESOLVE II Study

RESOLVE II is a study designed to evaluate whether a new investigational, dissolvable, steroid-releasing sinus product can reduce the symptoms of nasal blockage that return after endoscopic sinus surgery (ESS).

The sinus product is placed in the doctor’s office during a non-invasive procedure. The patient is awake during the procedure, and no cuts or incisions are made.

The study will enroll 300 patients who suffer from chronic sinusitis due to continued sinus blockage so severe that additional surgery is needed. The patients will be enrolled at up to 45 sites across the U.S.

Learn more about the sinus product.

Learn if you are eligible to participate in the study.
To see details of the study on ClinicalTrials.gov, please [click here](#).