

What is Balloon Sinuplasty™?

The painful symptoms associated with chronic sinusitis can be overwhelming. If symptoms are difficult to control with medications alone, your primary doctor may refer you to an Ear, Nose and Throat (ENT) specialist, who can determine the best course of treatment, including further medication therapy or surgery to open the sinus passage ways.

Now, there is an additional surgical option for treatment of blocked sinuses called *Balloon Sinuplasty™* Technology. If you have been diagnosed with chronic sinusitis and are not responding well to antibiotics you may be a candidate for surgery. Your surgeon now has a less invasive option that is clinically proven to be safe, effective and improve the quality of your life.

Balloon Sinuplasty™ Technology is an endoscopic, catheter-based system for patients suffering from sinusitis. The FDA-cleared technology uses a small, flexible, sinus balloon catheter to open up blocked sinus passageways, restoring normal sinus drainage. When the sinus balloon is inflated, it gently restructures and widens the walls of the passageway while maintaining the integrity of the sinus lining.

[Learn more](#) about *Balloon Sinuplasty™* Technology.

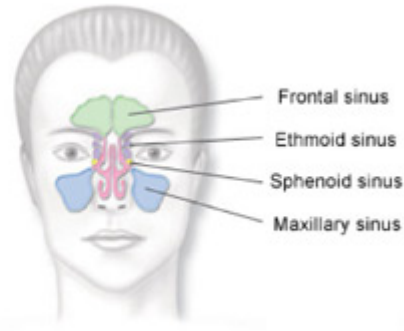
[Sources](#)

Balloon Sinuplasty™ Overview

Balloon Sinuplasty™ Technology provides surgeons with an endoscopic, catheter-based system to open blocked sinuses for patients suffering from sinusitis. Recently published data in the leading ENT journal shows that the technology is safe and effective: study participants experienced no adverse events and received statistically and clinically significant improvement in their symptoms.

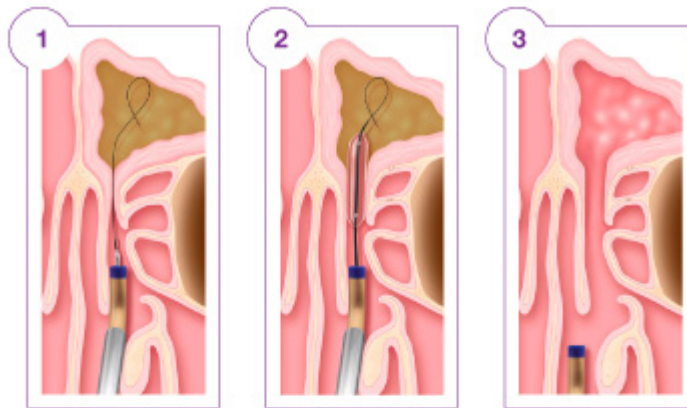
Balloon Sinuplasty™ Technology is used by qualified Ear, Nose, and Throat (ENT) physicians and involves the use of tiny balloons to open blocked sinuses similar to how angioplasty uses balloons to open blocked coronary arteries.

The diagram below shows an inflamed left frontal sinus.



During sinus surgery, an ENT physician will use *Balloon Sinuplasty™* devices to open the blockage that is preventing sinus drainage.

The following picture summarizes the steps associated with using the *Balloon Sinuplasty™* Technology:



1
Gain Access to the Sinus

To gain initial sinus access, our sinus guide catheter is introduced into the nasal cavity to target the sinus ostia under endoscopic visualization. Our sinus guide-wire or our sinus illumination system is introduced through the sinus guide catheter and gently advanced into the target sinus.

2
Inflate Balloon Across Ostium

The sinus balloon catheter is introduced over the sinus guide-wire or sinus illumination system and positioned across the blocked ostium. The position of the sinus balloon catheter is confirmed and the balloon is gradually inflated to open and remodel the narrowed or blocked ostium.

3
Deflate and Remove Balloon

The sinus balloon catheter is then deflated and removed, leaving the ostium open allowing the return of sinus drainage. There is little to no disruption to mucosal lining.

[Learn more](#) about the benefits of using *Balloon Sinuplasty™* Technology.

Balloon Sinuplasty™ Benefits

The benefits of *Balloon Sinuplasty™* Technology:

- **Safe and Effective**
While use of any surgical instrument involves some risk, clinical research has indicated the *Balloon Sinuplasty™* System to be safe and effective in improving symptoms of sinusitis.
- **Minimally Invasive**
The technology uses small, soft, flexible devices that enter entirely through the nostrils. These devices gently open blocked sinus openings, and in many cases, without tissue or bone removal.
- **Minimal Bleeding**
Because in many instances no tissue or bone is removed when using this technology, there may be little bleeding associated with the procedure.
- **Quick Recovery Time**
While recovery time varies with each patient, many people can quickly return to normal activities.
- **Does Not Limit Treatment Options**
This technology is an endoscopic tool and may be used with other medical therapies or sinus surgery techniques. It does not limit future treatment options if you have progressive disease.

Intended for use by or under the direction of a physician. *Balloon Sinuplasty™* Technology has associated risks, including tissue and mucosal trauma, infection, or possible optic injury. Consult your physician for a full discussion of risks and benefits to determine whether this procedure is right for you.

[Sources](#)

Sinusitis and Balloon Sinuplasty™ FAQs

How do I find an ENT physician in my area that is trained to use *Balloon Sinuplasty™* devices?

[Click here](#) to get a list of doctors in your area trained on the use of the technology.

What is sinusitis?

Sinusitis is an inflammation of the sinus lining. If the sinus opening becomes swollen shut, normal mucus drainage may not occur, and this may lead to infection and inflammation of the sinuses.

What are the common symptoms of sinusitis?

Common symptoms include:*

- Facial pain, pressure, congestion or fullness
- Difficulty breathing through the nose

- Discharge of yellow or green mucus from the nose
- Teeth pain
- Loss of the sense of smell or taste
- Headache
- Fatigue
- Sore throat
- Bad breath

What types of doctors treat sinusitis?

Many types of doctors treat sinusitis, including general and family practice physicians, pediatricians, and allergists. However, if you have chronic sinusitis or do not respond to medical treatment, you may be referred to a specialist - an Ear, Nose, and Throat (ENT) physician, or Otolaryngologist.

How is sinusitis treated?

Various approaches have emerged for surgeons to consider when treating sinusitis patients:

- Medical therapy
- Endoscopic sinus surgery with cutting instruments
- Endoscopic sinus surgery with balloon catheters

Medical Therapy

Sinusitis is typically treated first with medication. Treatment with antibiotics or topical nasal steroid sprays is successful for many sinusitis sufferers. Inhaling steam or use of saline nasal sprays or drops can also help. However, at least 20% of patients do not respond adequately to medications.

Endoscopic Sinus Surgery (with cutting instruments)

Sinus surgery aims to clear blocked sinuses and restore normal sinus drainage. The procedure removes bone and tissue to enlarge the sinus opening. The removal of bone and tissue may lead to pain, scarring, and bleeding.

Endoscopic Sinus Surgery (with *Balloon Sinuplasty*[™] Technology)

The technology utilizes a small, flexible, Sinus Balloon that is placed into the nose to reach the sinuses. The Sinus Balloon is gradually inflated to gently restructure the previously blocked sinus opening which helps to restore normal sinus drainage and function. There is minimal bleeding, and many patients have been able to quickly return to normal activities. Clinical research has indicated that the *Balloon Sinuplasty*[™] System is a safe and effective instrument in dilating blocked sinuses.

[Read more](#) about *Balloon Sinuplasty*[™] Technology.

What is the *Balloon Sinuplasty*[™] System?

The *Balloon Sinuplasty*[™] System is the name used for a group of medical devices that are used to create openings in your sinuses. The devices use a small, flexible balloon that is placed into the nose to reach the sinuses. The balloon is gradually inflated to gently restructure the previously blocked nasal passage, restoring normal sinus drainage.

What are the *Balloon Sinuplasty*[™] devices?

The *Balloon Sinuplasty*[™] devices are FDA-cleared, endoscopic, catheter-based instruments specifically designed to

be used in sinus surgery. The Sinus Balloon Catheter is gradually inflated to gently restructure the previously blocked sinus opening, which restores normal sinus drainage, without damaging the sinus.

Does surgery with the *Balloon Sinuplasty*™ Technology work?

Clinical research has indicated that using *Balloon Sinuplasty*™ Technology is safe and effective in dilating sinus openings.

How long does symptom relief last after surgery with *Balloon Sinuplasty*™ Technology?

Results vary by individual. Published clinical data has shown the following regarding patients who have had sinus surgery with *Balloon Sinuplasty*™ Technology:

- A study of 1,036 patients at multiple institutions reported that sinus symptoms improved in 96% of patients at an average follow-up period of 10 months.*
- Another study followed 65 patients at multiple institutions and reported clinically and statistically significant improvement in patient symptoms out to 2 years.*

How do sinus openings stay open after surgery with *Balloon Sinuplasty*™ Technology?

Balloon Sinuplasty™ Technology dilates sinus openings, or *ostia* by pushing aside bones which comprise the sinus ostia. Moving bone remodels the sinus ostia, creating wider openings.

Are the *Balloon Sinuplasty*™ devices safe?

The *Balloon Sinuplasty*™ Technology is minimally invasive and has been clinically demonstrated to be safe by leading Ear, Nose and Throat doctors. Finally, unlike other tools used to clear blocked sinus openings, *Balloon Sinuplasty*™ Technology does not remove any bone or tissue and many patients can quickly return to normal activities.

What are the risks of surgery with *Balloon Sinuplasty*™ Technology?

Your healthcare provider can best explain the potential risks of surgery with *Balloon Sinuplasty*™ Technology. In all published clinical data, no serious adverse events attributable to the *Balloon Sinuplasty*™ System have been reported. Intended for use by or under the direction of a physician. *Balloon Sinuplasty*™ Technology has associated risks, including tissue and mucosal trauma, infection, or possible optic injury. Consult your physician for a full discussion of risks and benefits to determine whether this procedure is right for you.

How long does surgery with *Balloon Sinuplasty*™ Technology take?

The duration of the procedure varies by individual situations. Ask your healthcare provider for the most accurate answer.

In a study of 1,036 patients who underwent sinus surgery with *Balloon Sinuplasty*™ Technology at multiple institutions, an average procedure time was 3 hours, including the surgery and post-anesthesia recovery time.* None of the patient required an overnight stay at the hospital.

Will I require general anesthesia for surgery with *Balloon Sinuplasty*™ Technology?

Most patients undergo general anesthesia for sinus surgery with *Balloon Sinuplasty*™ Technology, but some patient have had the procedure under local anesthesia. Your healthcare provider can best advise you on your anesthesia options.

How long does it take to recover from a typical surgery using the *Balloon Sinuplasty*[™] System?

Because the system is minimally invasive it is typically used in an outpatient setting. While recovery time will vary from patient to patient, many people can quickly return to normal activities.

Does surgery with *Balloon Sinuplasty*[™] devices limit my treatment options?

No. *Balloon Sinuplasty*[™] devices are endoscopic tools used within conventional sinus surgery and may be used with other medical therapies. They do not limit future treatment options for patients.

Are *Balloon Sinuplasty*[™] devices right for me?

If you suffer from sinusitis, and medication alone has not been effective in relieving your symptoms, you may be a candidate for surgery using the *Balloon Sinuplasty*[™] devices. To find out if you are a candidate for the *Balloon Sinuplasty*[™] devices, [click here](#). We also encourage you to talk to your doctor about whether use of these FDA-cleared, endoscopic, catheter-based tools is right for you.

Who uses *Balloon Sinuplasty*[™] devices?

Ear, Nose, and Throat physicians who have been trained on the *Relieva Balloon Sinuplasty*[™] devices.

Are *Balloon Sinuplasty*[™] devices covered by Medicare?

Yes. Medicare covers endoscopic sinus surgery when any combination of tools, including a balloon catheter, is used to perform the procedure.

Are *Balloon Sinuplasty*[™] devices covered by other insurance carriers?

Most insurance companies cover sinus surgery with *Balloon Sinuplasty*[™] devices. To be certain of your coverage, contact your insurance provider to find out your specific coverage policy.

What are patients saying about sinus surgery with *Balloon Sinuplasty*[™] Technology?

[Click here](#) to see what other patients are saying about their experiences with the *Balloon Sinuplasty*[™] Technology.

What are physicians saying about sinus surgery with *Balloon Sinuplasty*[™] Technology?

[Click here](#) to see what doctors are saying about their experiences with the *Balloon Sinuplasty*[™] Technology.

[*Sources](#)

Balloon Sinuplasty[™] Technology is intended for use by or under the direction of a physician. *Balloon Sinuplasty*[™] Technology has associated risks, including tissue and mucosal trauma, infection, or possible optic injury. Consult your physician for a full discussion of risks and benefits to determine whether this procedure is right for you.