



BALLOON SINUPLASTY FACT SHEET

Balloon Sinuplasty for Chronic Sinusitis Relief

Balloon Sinuplasty is a breakthrough procedure that relieves the pain and pressure associated with chronic sinusitis. It is used by surgeons to safely and effectively treat chronic sinusitis patients who are not responding well to medications such as antibiotics, nasal steroids, or over-the-counter (OTC) drugs, and are seeking relief from uncomfortable and painful sinusitis symptoms.

Similar to how angioplasty uses balloons to open blocked arteries, Balloon Sinuplasty, a system of catheter-based instruments, opens blocked sinuses.

The procedure is less invasive than traditional sinus surgery. It allows most patients to return to normal activities quickly within 48 Hours.¹

With Balloon Sinuplasty, a specially-designed catheter is inserted into the nose to reach the blocked sinus cavity. A small balloon is slowly inflated, which widens and restructures the walls of the sinus passage, helping to drain mucus from the blocked sinus and restore normal sinus drainage without cutting and with minimal bleeding. This approach also preserves the natural structure of the sinuses.

Published clinical data shows that Balloon Sinuplasty provides symptom relief for the majority of patients:

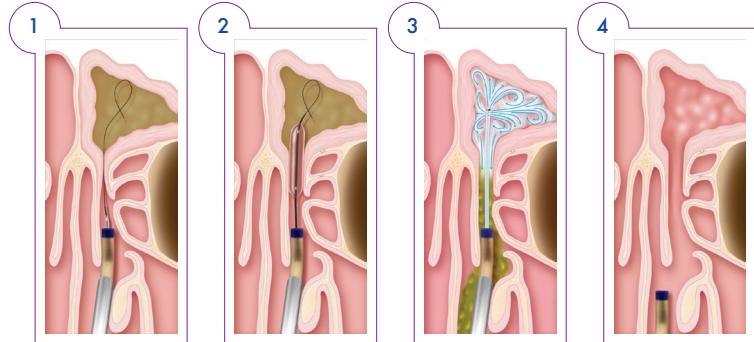
In the operating room:

- A multi-center study of 1,036 patients who had Balloon Sinuplasty reported that sinus symptoms improved in 95 percent of patients at an average follow-up period of 9 months.²
- Another multi-center study followed 65 patients who had Balloon Sinuplasty and reported clinically and statistically significant improvement in patient symptoms out to two years.³

In the office:

Acclarent office-based sinus dilation is:

- Safe and effective, with clinically and statistically significant improvement in symptom and radiographic scores
- Practical, with 93.2% of sinuses successfully dilated and evidence suggesting suitability for patients with mild/moderate ethmoid disease
- Compelling for patients, with the majority of patients returning to normal activity within 2 days of the procedure.⁴
- At the 1 year follow up, following office-based balloon sinuplasty, significant improvements in quality of life observed at 24 weeks were maintained at 1 year post-surgery. These extended results provide further evidence of office-based Balloon Sinuplasty as an effective, minimally invasive procedure for appropriately selected patients with CRS.⁵



Balloon Sinuplasty opens blocked sinus cavities in four easy steps:

- 1) A guide wire and balloon catheter are inserted into the inflamed sinus.
- 2) The balloon is inflated to expand the sinus opening.
- 3) Saline is sprayed into the infected sinus cavity to flush out pus and mucus.
- 4) The system is removed, leaving the sinuses open.



When compared to Medical Management:

- In a multi-center study of 198 Chronic Rhinosinusitis (CRS) patients, who previously failed medical management, over 74 percent chose Balloon Sinuplasty over medical management alone.
- Balloon Sinuplasty provided superior Quality of Life outcomes over medical management across all three validated scales (SNOT20, CSS, RSDI).
- Balloon Sinuplasty as a stand-alone procedure also provided superior outcomes.
- There was a 97.6 percent technical success rate dilating the targeted sinuses.⁶
- In a second multi-center study involving Recurrent Acute Rhinosinusitis (RARS) patients, Balloon Sinuplasty with Medical Management was found to be superior to Medical Management alone in enhancing Quality of Life (QOL) for RARS patients. Balloon Sinuplasty with Medical Management should be considered as a viable treatment option for properly diagnosed RARS patients.⁷

Balloon Sinuplasty is performed under general anesthesia in an outpatient setting; however, some surgeons are choosing to treat certain patients in their office under local anesthesia. The reported complication rate for Balloon Sinuplasty is low.

Patients who suffer from chronic sinusitis and are not responding well to medications may benefit from seeing an Ear, Nose, and Throat (ENT) physician who performs Balloon Sinuplasty to determine if the procedure is right for them. Most insurance companies and Medicare provide coverage for Balloon Sinuplasty.

For more information about Balloon Sinuplasty, visit www.acclarent.com.

ACCLARENT® Balloon Sinuplasty Devices are intended for use by or under the direction of a physician who is trained in the use of Acclarent Technology. ACCLARENT® Balloon Sinuplasty Device use has described risks, including tissue and mucosal trauma, infection, or possible orbital injury. Prior to use, it is important to read the Instructions for Use and to understand the contraindications, warnings, and precautions associated with these devices, as well as all products mentioned on this resource.

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Sources

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