

Acclarent : *Balloon Sinuplasty*[™]

Key Messages for Consumer Health and Trade Media

Procedure/MOA Message

Balloon Sinuplasty is a breakthrough procedure that relieves the pain and pressure associated with chronic sinusitis.

- Symptoms include drainage of a thick, yellow or greenish discharge from the nose or down the back of the throat, nasal obstruction or **congestion**, tenderness and swelling around the eyes, cheeks, nose and forehead, and/or a reduced sense of smell and taste.
- Medications could include **antibiotics**, **nasal steroids**, and over-the-counter (OTC) medicines.
- According to published studies, up to 60 percent of chronic sinusitis patients are not successfully treated with medication.¹ Published clinical studies have shown that sinus **symptoms** improved in 95 percent of patients who had *Balloon Sinuplasty* in the operating room at an average follow-up period of 9 months, and clinically and statistically significant improvement in patient symptoms was observed out to two years.²⁻³
- *With Balloon Sinuplasty*, a specially-designed **catheter** is inserted into the nose to reach the inflamed sinus. A small **balloon** is slowly inflated, which widens and restructures the walls of the **sinus passage** without cutting and with minimal bleeding, helping to drain mucus from the blocked sinus and restore normal mucus flow. The balloon is then removed, leaving the sinuses open.
- *Balloon Sinuplasty* opens blocked sinuses yet preserves the natural structure of the sinuses.
- The impact of chronic sinusitis on a person's quality of life could include throbbing facial pain or pressure, **headaches**, bad breath, irritability, fatigue or nausea, and pain in the upper teeth.⁴ Patients who suffer from chronic sinusitis and are not responding well to medications may want to see an **Ear, Nose, and Throat (ENT)** physician who performs *Balloon Sinuplasty* to determine if the procedure is right for them.

Less Invasive/Recovery Message

- *Balloon Sinuplasty* is less invasive than conventional sinus surgery. It **allows patients to quickly return** to normal activities.⁵
- *Conventional sinus surgery*, known as functional endoscopic sinus surgery or FESS, is considered only if medical treatment fails or if there is a nasal and/or sinus obstruction that cannot be corrected with medication. FESS aims to clear blocked sinuses and restore normal sinus **drainage** by removing bone and tissue to enlarge the sinus opening, which may lead to pain, scarring, and bleeding.
- *With Balloon Sinuplasty*, a specially-designed **catheter** is inserted into the nose to reach the inflamed sinus cavity. A small **balloon** is slowly inflated, which widens and restructures the walls of the sinus **passage** without cutting and with minimal bleeding, helping to drain mucus from the blocked sinus and restore normal mucus flow. The balloon is then removed, leaving the sinuses open.

- *Balloon Sinuplasty* is usually performed under general anesthesia in an outpatient setting; however, some **surgeons** are now choosing to treat certain patients in their office under **local anesthesia**.
- Ninety-five percent of patients who have had *Balloon Sinuplasty* in an office setting say they would have it again.⁶
- Some physicians may use *Balloon Sinuplasty* to less-invasively open blocked sinus passages in combination with functional endoscopic sinus surgery (FESS) for patients who have advanced chronic sinusitis or other complications.

Safety Message

- The reported complication rate for *Balloon Sinuplasty* is low.⁷ *Balloon Sinuplasty* has proven to be a safe and effective procedure.
- *Balloon Sinuplasty* is intended for use by or under the direction of a doctor. There are associated risks, including tissue and mucosal trauma, infection or possible optic injury. Interested individuals should speak with their doctor about the risks and benefits and to determine whether *Balloon Sinuplasty* is right for them.

Chronic Sinusitis

- Sinusitis affects 37 million Americans each year,⁸⁻⁹ making it one of the most common health problems.
 - More Americans suffer from sinusitis than diabetes, asthma or coronary heart disease.¹⁰
- With sinusitis, the cavities of the sinuses become inflamed and **swollen** and prevent normal **mucus drainage**, causing **mucus** and **pressure** to build up.
- Sinusitis symptoms include:¹¹
 - drainage of a thick, yellow or greenish discharge from the nose or down the back of the throat
 - nasal obstruction or **congestion**
 - or tenderness and swelling around the eyes, cheeks, nose and forehead.
- The impact of chronic sinusitis on a person's quality of life could include throbbing facial pain or headaches, difficulty breathing and sleeping, bad breath, irritability, fatigue, nausea and loss or reduced sense of taste.¹²
- Sinusitis that lasts longer than 12 weeks is known as chronic sinusitis.
- Otolaryngologists, commonly referred to as ENT (Ear, Nose, and Throat) physicians, treat conditions of the ears, nose, throat and related structures of the head and neck; this would include chronic sinusitis.
- Individuals who think they may have chronic sinusitis should ask their **general practitioner** or **primary care physician** to recommend or refer them to an Ear, Nose and Throat physician (an **otolaryngology** specialist).
 - Patients report they often confuse sinus infection symptoms with allergy symptoms. This means patients may not be getting optimal care for their condition.¹³
 - Individuals who experience frequent sinus infections may be prone to developing chronic sinusitis.
- An ENT physician may use several methods to help screen for chronic sinusitis: visual inspection, nasal endoscopy, **CT scan**, and/or nasal and sinus cultures.

- When a chronic sinusitis diagnosis is made by an ENT physician, patients are treated with medication, e.g., nasal steroid sprays, antibiotics, or oral steroids to relieve symptoms.
- It is estimated that up to 60 percent of chronic sinusitis sufferers are not successfully treated with medication.¹
- Patients who do not respond well to medications become candidates for conventional sinus surgery.

* Key search terms are indicated in **purple** and should be used in media materials to improve search for *Balloon Sinuplasty*; **bold** copy highlights various key messages for easier review

Sources

¹ Hamilos, D. Chronic sinusitis. *J Allergy Clin Immunol* 2000; 106: 213-227; Stankiewicz, J., et al., Cost Analysis in the Diagnosis of Chronic Rhinosinusitis. *Am J Rhinol* 2003;17(3): 139-142; Subramanian, H., et al. A Retrospective Analysis of Treatment Outcomes and Time to Relapse after Intensive Medical Treatment for Chronic Sinusitis. *Am J Rhinol* 2002; 16(6): 303-312; Hessler, J., et al. Clinical outcomes of chronic rhinosinusitis in response to medical therapy: Results of a prospective study. *Am J Rhinol* 2007; 21(1): 10-18; Lal, D., et al. Efficacy of targeted medical therapy in chronic rhinosinusitis, and predictors of failure. *Am J Rhinol Allergy* 23, 396-400, 2009.

² Levine, et al. Multicenter Registry of Balloon Catheter Sinusotomy Outcomes for 1,036 Patients, *Annals of Otolaryngology, Rhinology, and Laryngology*, 2008, Vol. 117, pp. 263-270.

³ Weiss, et al. "Long-term outcome analysis of balloon catheter sinusotomy: Two-year follow-up." *Otolaryngology-Head and Neck Surgery*, 2008, Vol. 139, pp. S38-S46.

⁴ <http://www.entnet.org/healthinformation/sinusitis.cfm> (Accessed July 19, 2011)

⁵ Wynn, R. and Vaughan, W. "Post-op Pain after FESS with BST" poster AAO 2006.

⁶ ORIOS I, office-based dilation, Data on file #006.

⁷ Levine, et al. *ibid.*

⁸ Benninger, M. et al. Adult chronic rhinosinusitis: Definitions, diagnosis, epidemiology, and pathophysiology. *Otolaryngol Head Neck Surg* 2003; 129S: S1-S32.

⁹ Lusk R, Bothwell MR, Piccirillo J. Long-term follow-up for children treated with surgical intervention for chronic rhinosinusitis. *Laryngoscope* 2006; 116:(12) 2099-2107.

¹⁰ Adams, PF, Hendershot GE, and Marano MA. Current estimates from the National Health Interview Survey, 1996. National Center for Health Statistics. *Vital Health Stst* 10(200). 1999.

¹¹ <http://www.entnet.org/healthinformation/sinusitis.cfm> *ibid.*

¹² <http://www.entnet.org/healthinformation/sinusitis.cfm> *ibid.*

¹³ <http://www.aafa.org/sinusitis>