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.
o **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.

o Ninety-five percent of patients who have had **Balloon Sinuplasty** in an office setting say they would have it again.  

o 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.  
  **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, making it one of the most common health problems.
  o More Americans suffer from sinusitis than diabetes, asthma or coronary heart disease.

- 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:
  o drainage of a thick, yellow or greenish discharge from the nose or down the back of the throat
  o nasal obstruction or congestion
  o 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.

- 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).
  o Patients report they often confuse sinus infection symptoms with allergy symptoms. This means patients may not be getting optimal care for their condition.
  o 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.

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• 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


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

⁷ Levine, et al. ibid.


¹³ http://www.aafa.org/sinusitis