Balloon Sinuplasty Procedure:

Sinusitis is one of the most common, chronic health problems in the U.S., afflicting an estimated 30 million Americans each year. Patients with chronic rhinosinusitis can suffer from facial pain and pressure, headaches, congestion, nasal discharge, a decreased sense of smell or taste and fatigue, among other symptoms.1 Sinusitis has a significant effect on these patients' physical, functional, and emotional quality of life.

Historically, chronic rhinosinusitis patients were limited to two treatment options: continued medical therapy, including antibiotics and topical nasal steroids, or conventional sinus surgery such as Endoscopic Sinus Surgery (ESS). Many chronic sinusitis sufferers do not get relief with medication. Conventional sinus surgery in the operating room may include cutting and removal of bone and tissue, general anesthesia, and an extended recovery period.

In 2005, an innovative technology called Balloon Sinuplasty was introduced. This provided chronic sinusitis patients with a minimally invasive option to traditional sinus surgery. Balloon Sinuplasty devices, originally designed and developed by Acclarent, utilize a soft, flexible guidewire and small balloon catheter that are placed through the nose into the blocked sinus passageway. The balloon is then inflated to gently restructure and open the sinus passageway, restoring normal sinus drainage and function.

The Acclarent Balloon Sinuplasty technology is proven safe and effective and has been used to treat more than 510,000 patients, in over 560,000 procedures since receiving FDA clearance.2

Since the beginning of 2011, Balloon Sinuplasty has been offered as an in-office procedure that eliminates the need for general anesthesia. Selection for the in-office Balloon Sinuplasty procedure is dependent upon the patient's condition, procedure needed and the appropriateness of local anesthesia. This innovative, office procedure allows patients to return to work and normal activities within 48 hours after the procedure.3 In a recent study, over 74 percent of patients chose Balloon Sinuplasty over medical management alone.4 The Acclarent Balloon Sinuplasty devices have been used in well over 88,000 in-office procedures.2

For Patients: Acclarent® Technology is intended for use by or under the direction of a physician. Acclarent® 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.

References

1 Rosenfeld, R.M., Piccirillo, J.F., Chandrasekhar, S.S., et al. (2015). Clinical Practice Guideline (Update): Adult Sinusitis. *Otolaryngology – Head and Neck Surgery,* 152(2S); S1–S39.

2 Acclarent Procedural Data Documented on 9-1-16.
3 Karanfilov, B., Silvers, S., Pasha, R., et al. (2013). Office-based balloon sinus dilation: a prospective, multicenter study of 203 patients. *Int Forum Allergy Rhinol*, 3; 404-411.
4 Payne, S.C., Stolovitzky, P., Mehendale, N., et al. (2016). Medical therapy versus sinus surgery by using balloon sinus dilation technology: A prospective multicenter study. *American Journal of Rhinology & Allergy, 30;* 279-286.