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New Studies Confirm Safety, Effectiveness of *Balloon Sinuplasty*™ Technology for Chronic Sinusitis

Patients show significant improvement through 2-year follow-up

MENLO PARK, CA – September 22, 2008 – Two multicenter studies published this week in **Otolaryngology - Head and Neck Surgery** confirm *Balloon Sinuplasty*™ technology is safe and effective when used by physicians to treat chronic sinusitis patients.

The foundation for those studies was a six-month clinical trial called CLEAR that began in 2005. It included 109 patients who had minimally invasive sinus surgery with the *Balloon Sinuplasty*™ technology. They participated in one-year and two-year follow-up studies which reported:

- 92% functional patency at one-year follow-up.
- At two-year follow-up, 85% of patients reported improvement in their sinus symptoms. No patient's condition worsened.
- Clinically and statistically significant improvements in patient quality of life maintained at one and two year follow-up.
- No serious adverse events observed at any time point throughout the study.

Balloon Sinuplasty™ technology is used to restore normal sinus drainage by widening constricted sinus passages with specially designed catheters and balloons. The technology has been used to treat tens of thousands of patients since receiving FDA clearance in 2005 and can be used alone or with standard surgical instrumentation.

The Center for Disease Control data reports sinusitis is among the most common illnesses in the U.S., affecting an estimated 37 million Americans and leading to 500,000 surgeries a year. Symptoms include repeated infections, headaches, facial pain, persistent congestion and unrelenting fatigue.

"The goal of sinus surgery is to open the sinuses so they can function normally, while preserving as much natural anatomy as possible. With *Balloon Sinuplasty*™ technology, we are able to accomplish that goal with our current approach in a true minimally invasive way, and give our patients the relief they have been seeking," said Frederick A. Kuhn, M.D. of the Georgia Nasal and Sinus Institute in Savannah, and lead author of the one-year outcomes study.

"These multi-year data continue to affirm the safety and effectiveness of *Balloon Sinuplasty*™ technology. Patients can feel confident that this technology truly provides significant, durable improvement in sinus symptoms and overall quality of life," said otolaryngologist Raymond Weiss, M.D. of the Sinus Center of the South in Biloxi, and lead author of the two-year study.

Recovery times vary after sinus surgery, but patients typically return to normal activities within 24 hours of treatment. Since 2005, more than 5,000 sinus surgeons have been trained to use *Balloon Sinuplasty*™ technology.

Bill Facteau, President and CEO of Acclarent, Inc. said, "We are very pleased with the 1- and 2-year results of the CLEAR Study. It is evident from these data that when *Balloon Sinuplasty*™ devices are used in sinus surgery they are safe, effective, and significantly improve a patient's quality of life."

About Acclarent

Acclarent, Inc. is a privately held medical device company located in Menlo Park, CA. Its singular focus is improving patient care in all areas of otolaryngology by developing and producing

medical devices solely for Ear, Nose and Throat (ENT) specialists and their patients. Acclarent is demonstrating this by developing innovative technologies, and investing in clinical studies and physician training. For more information, visit www.acclarent.com or www.BalloonSinuplasty.com.