

Corporate Fact Sheet

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Profile: BÂRRX Medical, Inc. develops solutions for treating a precancerous condition of the lining of the esophagus (swallowing tube) called Barrett's esophagus as well as other technologies to treat various precancerous conditions of the gastrointestinal tract.

Ownership: Founded in June 2000, BÂRRX Medical, Inc. is privately-held.

Office: Corporate headquarters are located in Sunnyvale, California.

Technology: The HALO System is the first in a new generation of ablation instruments to treat Barrett's esophagus, a condition that results from chronic exposure of the esophagus to the contents of the stomach, which is commonly referred to as gastroesophageal reflux disease, or GERD. Left untreated, it can progress to a dangerous type of esophageal cancer called adenocarcinoma.^{1,2} The HALO ablation system has two specialized products to fit the needs of the treatment; The HALO³⁶⁰ and HALO⁹⁰ System. The HALO³⁶⁰ provides treatment for large segments of Barrett's esophagus and results in a uniform and controlled circumferential ablative therapy, which can remove a thin layer of diseased tissue and allow the regrowth of normal cells without injuring healthy underlying tissue. The HALO⁹⁰ System is designed for focal ablation of Barrett's and can be used independently or in conjunction with the HALO³⁶⁰ System.

It is uniquely able to treat small areas of Barrett's esophagus. Following ablation with either the HALO³⁶⁰ or the HALO⁹⁰ System the diseased tissue in most patients is replaced by new healthy tissue within three to four weeks.

¹ Spechler SJ. Barrett's esophagus. N Engl J Med 2002; 346: 836-842.

² Reid B.J and Weinstein W. M. Barrett's esophagus and adenocarcinoma. Gastroenterology Clinics of North America 1987; 38: 477-492.



The HALO³⁶⁰ System has three components: a sizing balloon, an ablative energy generator and an ablation catheter. The original HALO³⁶⁰ System was cleared by the FDA in 2001 and became commercially available in the U.S. in January 2005.

Initially, a sizing balloon is used to size the esophagus. A correctly sized ablation catheter is then inflated within the area of the intestinal metaplasia. The HALO³⁶⁰ energy generator is activated to deliver a rapid burst of ablative energy which removes (ablates) a very thin layer of the diseased esophagus. This energy delivery is controlled so as to avoid injury to the normal, healthy underlying tissues. New healthy tissue replaces the ablated Barrett's tissue in three to four weeks for most patients. The procedure, which in clinical studies had a median procedure time of 26 minutes, is performed without incisions using conscious sedation in an out-patient setting.

The HALO⁹⁰ System has two components: an ablative energy generator and an ablation catheter featuring a small electrode that can be mounted on the end of an endoscope. The HALO⁹⁰ system was cleared by the FDA in 2006 and became commercially available in the U.S. in January 2007. Using standard endoscopic skills, the physician directs the ablation catheter to the diseased area of the esophagus. The HALO energy generator is then activated to deliver a short burst of ablative energy, which removes a very thin layer of the diseased esophagus. The procedure, which in clinical studies had a median procedure time of 15 minutes, is performed without incisions using conscious sedation in an out-patient setting.

Study Results: Data from several multi-center clinical trials demonstrate median biopsy clearance rates of greater than 90 percent. The procedure was well tolerated by patients. In the longest follow up clinical study, greater than 98.4 percent of participants were Barrett's-free after one to two treatment sessions after 30 months follow up.

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