



Breast Reconstruction at the Speed of Life

Clinical Data Overview

About the AeroForm® Tissue Expander System

Clinical data have shown that with AeroForm, patients achieve full expansion and complete their reconstruction much faster than with traditional, saline-based expanders. The device has been evaluated in five clinical trials and 13 peer-reviewed publications including *The Annals of Plastic Surgery*, *Plastic and Reconstructive Surgery* and the *Journal of Plastic, Reconstructive, & Aesthetic Surgery*.

- The [XPAND](#) study compared AeroForm to traditional saline expanders in a randomized, controlled trial that included 150 patients across 17 sites in the U.S. The full results of the study were published in the December 2016 issue of *Plastic and Reconstructive Surgery*, the official journal of the American Society of Plastic Surgeons. The abstract of the published XPAND data is available [here](#). Trial data demonstrated that with AeroForm, patients:
 - ✓ Completed tissue expansion in 21 days, compared to 46 days for the saline group
 - ✓ Completed the reconstruction process one-month faster than the saline group
 - ✓ Achieved successful exchange to a long-term breast implant 98% of the time, and with a similar safety profile as the saline group
 - ✓ Reported the device was easy to use in 98% of cases
- The [ASPIRE](#) trial, published in the *Journal of Plastic, Reconstructive and Aesthetic Surgery*, demonstrated that in 21 patients (13 of who underwent bilateral procedures), the overall success rate for AeroForm was 94% with no device-related reconstruction failures.
- The [PACE 2](#) trial, published in *Plastic and Reconstructive Surgery*, demonstrated that in 33 patients, the average time to achieve desired expansion with AeroForm was 17 days. The vast majority of patients (97%) and the surgeon (94%) reported that the dosage controller was easy to use.

About Breast Cancer

- In 2016, an estimated 246,660 new cases of invasive breast cancer will be diagnosed in U.S. women, along with 61,000 new cases of non-invasive (in situ) breast cancer, according to the American Cancer Society.¹
- Breast cancer is the second-leading cause of death in women; an estimated 40,450 U.S. women will die from the disease in 2016, according to the American Cancer Society.²
- 1 in 8 women will develop breast cancer during her lifetime, according to the National Cancer Institute.³
- The rate of U.S. women undergoing mastectomies increased 36 percent between 2005 and 2013, according to data from the Agency of Healthcare Research and Quality.⁴
- The number of women having bilateral, or double mastectomies, is rising. The rate of female breast cancer patients undergoing the surgery more than tripled from just under 4 percent in 2002 to nearly 13 percent in 2012, according to data analyzed by researchers at Brigham and Women's Hospital.⁵

About Breast Reconstruction

- About 42% of women who have had a mastectomy will choose to have reconstructive surgery, as described in a 2014 study published in *JAMA Surgery*.⁶
- 1 in 5 women who do not undergo breast reconstruction following mastectomy reported a lack of knowledge about the procedure, according to a 2014 *JAMA Surgery* study.⁷

¹ American Cancer Society. Key Statistics about Breast Cancer, 2016. Available at: <http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-key-statistics>

² BreastCancer.Org. U.S. Breast Cancer Statistics, 2016. Available at: http://www.breastcancer.org/symptoms/understand_bc/statistics

³ National Cancer Institute. Breast Cancer Risk in American Women, 2012. Available at: <https://www.cancer.gov/types/breast/risk-fact-sheet>

⁴ Agency for Healthcare Research and Quality. "New Data Show Mastectomies Increased 36 Percent From 2005 to 2013," 2016. Available at: <http://www.ahrq.gov/news/newsroom/press-releases/2016/mastectomy-sb.html>

⁵Brigham and Women's Hospital. Rates of prophylactic mastectomy have tripled in past decade despite no survival benefit, 2016. Available at: <https://www.sciencedaily.com/releases/2016/03/160314090959.htm>

⁶ Morrow, M, et al. Access to Breast Reconstruction After Mastectomy and Patient Perspectives on Reconstruction Decision Making. *JAMA Surg.* 2014;149(10):1015-1021. doi:10.1001/jamasurg.2014.548.

⁷ Morrow, M, et al. Access to Breast Reconstruction After Mastectomy and Patient Perspectives on Reconstruction Decision Making. *JAMA Surg.* 2014;149(10):1015-1021. doi:10.1001/jamasurg.2014.548.

- In 2015, plastic surgeons in the United States performed a total of 106,338 breast reconstruction procedures, of which 77,219 (73%) involved tissue expansion for the reconstructive process.⁸
- 70% of the reconstructive breast procedures performed in 2015 were immediate reconstruction procedures, beginning at the time of mastectomy.⁹

⁸ ASPS. 2015 Plastic Surgery Statistics Report.

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