

The logo for AirXpanders features a stylized blue and grey shape on the left, resembling a drop or a leaf, followed by the word "AirXpanders" in a large, bold, black sans-serif font.

AirXpanders

Breast Reconstruction at the Speed of Life

About AirXpanders®

AirXpanders® is a U.S.-based medical device company focused on the design, manufacture, sale and distribution of the AeroForm® Tissue Expander System for patients undergoing breast reconstruction following mastectomy. AeroForm is a revolutionary needle-free, patient-controlled tissue expander which reduces the number of expansion visits to a plastic surgeon, and enables faster expansion than the current standard of care.

The company, headquartered in Palo Alto, Calif., was co-founded in 2005 by a Silicon Valley-based plastic surgeon. While on a bike ride, he got a flat tire and after inflating the tire using a CO₂ canister, he began to wonder if a similar technology could be applied to make the tissue expansion process easier and more comfortable for his breast reconstruction patients. This idea gave rise to the AeroForm device.

AeroForm was first granted CE marking in Europe in 2012, and approved for sale in Australia in 2014, where AirXpanders is publicly traded on the Australian Stock Exchange (ASX). AeroForm received *de novo* clearance from the U.S. Food and Drug Administration in December, 2016, and will initially be available in a limited market release to ensure optimal surgeon training and successful patient outcomes.

About AeroForm®

The AeroForm Tissue Expander System is a needle-free, patient-controlled tissue expander for use in two-stage breast reconstruction. The device is activated by the woman using a handheld wireless controller. The device is designed with pre-set limits so a woman can dose up to three 10cc doses of CO₂ per day, for a total of 30cc, based on her comfort. The controller administers small amounts of compressed carbon dioxide (CO₂) into the expander, to gradually stretch the skin to prepare a space for a breast implant. With the push of a button on the remote controller, a small amount of CO₂ is added to the expander quickly and comfortably, allowing the patient to continue with her daily activities.



For many patients, the thought of another painful breast procedure is a major barrier to having breast reconstruction surgery. AeroForm helps to decrease the anxiety associated with the process by offering a needle-free, patient-controlled option. Patients are able to achieve full tissue expansion in weeks rather than months, allowing them to rebuild their shape sooner following a mastectomy. It also means they spend

less time in their surgeons' office and more time recovering at home during their expansion.

Clinical data have shown that with AeroForm, patients achieve full expansion and progress to reconstruction much faster than with traditional, saline-based expanders. The device has been evaluated in five clinical trials and 13 peer-reviewed publications. The XPAND study, completed in the U.S., compared AeroForm to traditional saline expanders in a randomized, controlled clinical trial that included 150 patients across 17 sites in the U.S. The full results of the XPAND trial 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](#).

XPAND trial data demonstrated that with AeroForm, patients:

- Completed tissue expansion in 21 days, compared to 46 days for the saline group.
- Finished the reconstruction process one-month faster than the saline group.
- Achieved successful exchange to a long-term breast implant 98% of the time with a similar safety profile as the saline group.

Company Timeline

- 2005: AirXpanders founded and incorporated
- 2009: First human clinical trial completed in Australia
- 2011: First U.S. clinical trial commenced
- 2012: CE Mark secured in Europe
- 2014: AeroForm commercially available in Australia
- 2015: U.S. XPAND clinical trial completed, and met primary endpoints; results presented at American Society of Plastic Surgeons (ASPS) Meeting
- 2015: AirXpanders publicly listed on the Australian Stock Exchange (ASX)
- 2016: AeroForm receives U.S. FDA *de novo* clearance

AirXpanders Executive Team

Scott Dodson
President & CEO



Scott Murcay
CFO & COO



Anthony Carnemolla
VP of Sales



Tony Morefield
VP of Operations



Gwen Drain
Senior Director of Human Resources



Kathy Kelley
Senior Director of Clinical Affairs



Jennie Kim
Senior Director of Global Marketing



Mark Payne
Senior Director of Research &
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Vee Arya
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Belinda Pinedo
Director of Regulatory Affairs



