



# AirXpanders

*Breast Reconstruction at the Speed of Life*

## Frequently Asked Questions

### **What is breast reconstruction?**

Breast reconstruction is a surgical option for women who have had all or part of their breast removed. The surgery rebuilds the breast mound to the desired size and shape following the removal of the natural breast and can either be immediate, beginning at the time of mastectomy, or delayed, beginning weeks, months or years after the mastectomy.

### **How is reconstruction most commonly performed?**

Tissue expansion followed by placement of breast implants is the most common procedure for breast reconstruction, chosen by 73% of women who opt for reconstructive surgery. A temporary tissue expander is placed in the post-surgical skin envelope and inflated over time to create space for placement of breast implants. Once the skin and underlying muscle have been sufficiently stretched, the temporary tissue expander is surgically removed and a breast implant is placed.

### **How do tissue expanders work?**

Despite the frequent use of tissue expanders in reconstructive procedures, the expansion process has remained unchanged for more than 40 years. As it is traditionally performed, tissue expansion is a lengthy, painful process that uses needle-based saline expanders which require frequent visits to a plastic surgeon's office for expansion. With this approach, a plastic surgeon accesses a port on the expander via a needle through the skin in order to inject a volume of saline into the expander every one-to-three weeks for approximately three to six months. This results in numerous visits for the patient to the surgeon's office.

### **What is the AeroForm® Tissue Expander System?**

AeroForm is a revolutionary tissue expander that offers a needle-free alternative for tissue expansion to women who choose reconstructive surgery following a mastectomy. AeroForm is activated by a handheld wireless controller that administers small amounts of carbon dioxide (CO<sub>2</sub>) up to three times a day, to gradually stretch the tissue to prepare for a breast implant. With the push of a button from a remote controller, the programmed amount of CO<sub>2</sub> is delivered in seconds, allowing the patient to continue with her daily activities while preparing for reconstruction.

## **What are the benefits of AeroForm as compared to saline-based expanders?**

For many patients, the thought of another painful breast procedure involving needles is a major barrier to having breast reconstruction surgery. AeroForm helps to alleviate the anxiety associated with the expansion process with a needle-free, patient-controlled option. Patients are able to achieve full tissue expansion in weeks rather than months, allowing them to rebuild their breast sooner following a mastectomy. It also means they spend less time in their surgeons' office and get back to their lives faster following a mastectomy.

## **What data has been collected on AeroForm?**

The XPAND study, published in the December 2016 issue of *Plastic and Reconstructive Surgery*, compared AeroForm to traditional saline expanders in a randomized, controlled trial that included 150 patients across 17 sites in the U.S. Study data demonstrated that with AeroForm, patients were able to complete tissue expansion in 21 days, compared to 46 days for the saline group. In addition, AeroForm patients completed reconstruction one month sooner than the saline patients. The study also demonstrated both groups achieved successful exchange to a breast implant with a similar safety profile.

## **Who is a candidate for AeroForm?**

AeroForm is for women who have had or are having a mastectomy procedure and need to have tissue expansion for breast reconstruction. Women should not have an existing electronic medical device and may not undergo MRI with the expander in place. They should be able to understand and manage an at-home dosing protocol. Women should discuss AeroForm with their doctor, who can help determine if AeroForm is a good option.

## **How does AeroForm work?**

Following a mastectomy (frequently during the same surgical procedure), a plastic surgeon will place the AeroForm Tissue Expander underneath the skin and often the chest muscle. Once recovered from surgery and ready to begin expansion, a patient will turn on the dosage controller and move it slowly over the top portion of her breast to detect the expander. The controller is ready to deliver a dose when it emits a steady tone and four to five green lights appear. Holding the controller in place, she will press and release the button on the controller until an upbeat melody sounds, indicating that dosing is complete. After administering a dose, the controller will automatically turn off. The dosing process with AeroForm is completed in seconds.

## **When is AeroForm removed?**

A plastic surgeon will determine when expansion is complete and the patient is ready to receive long term breast implants. At that point, the tissue expander will be removed during a surgical procedure and a breast implant will be placed. The tissue expander is a temporary device which can remain in the patient for up to six months.

## **Who determines and sets dose limits for patients?**

Pre-set dose limits are programmed to prevent over-dosing of the expander. Each dose is set at 10 cc; with a maximum of three 10cc doses of CO<sub>2</sub> per day, for a total of 30cc. Once the expander is full, the device will limit the dosing to allow maintenance dosing only, if necessary.

### **How much does the AeroForm Tissue Expander System cost for patients?**

Federal law requires that both U.S. Medicare and private insurers, where they provide coverage for mastectomies, must also provide patients with reimbursement coverage for breast reconstruction procedures.

The U.S. Women's Health and Cancer Rights Act of 1998 secures mandatory reimbursement coverage for the medical costs associated with breast cancer. These include the costs associated with breast reconstruction following mastectomy. The Act also includes reimbursement coverage of breast reconstruction for women who decide to have preventative mastectomy of a non-affected breast due to genetic risk, family history, or as a result of cancer in the other breast.

### **Where is AeroForm available?**

AeroForm received de novo clearance from the U.S. Food and Drug Administration in December, 2016 and is available on a limited basis to ensure optimal training and maximize patient satisfaction. It was first granted CE marking in Europe in 2012, and approved for sale in Australia in 2014.

### **Who is AirXpanders, Inc.?**

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.