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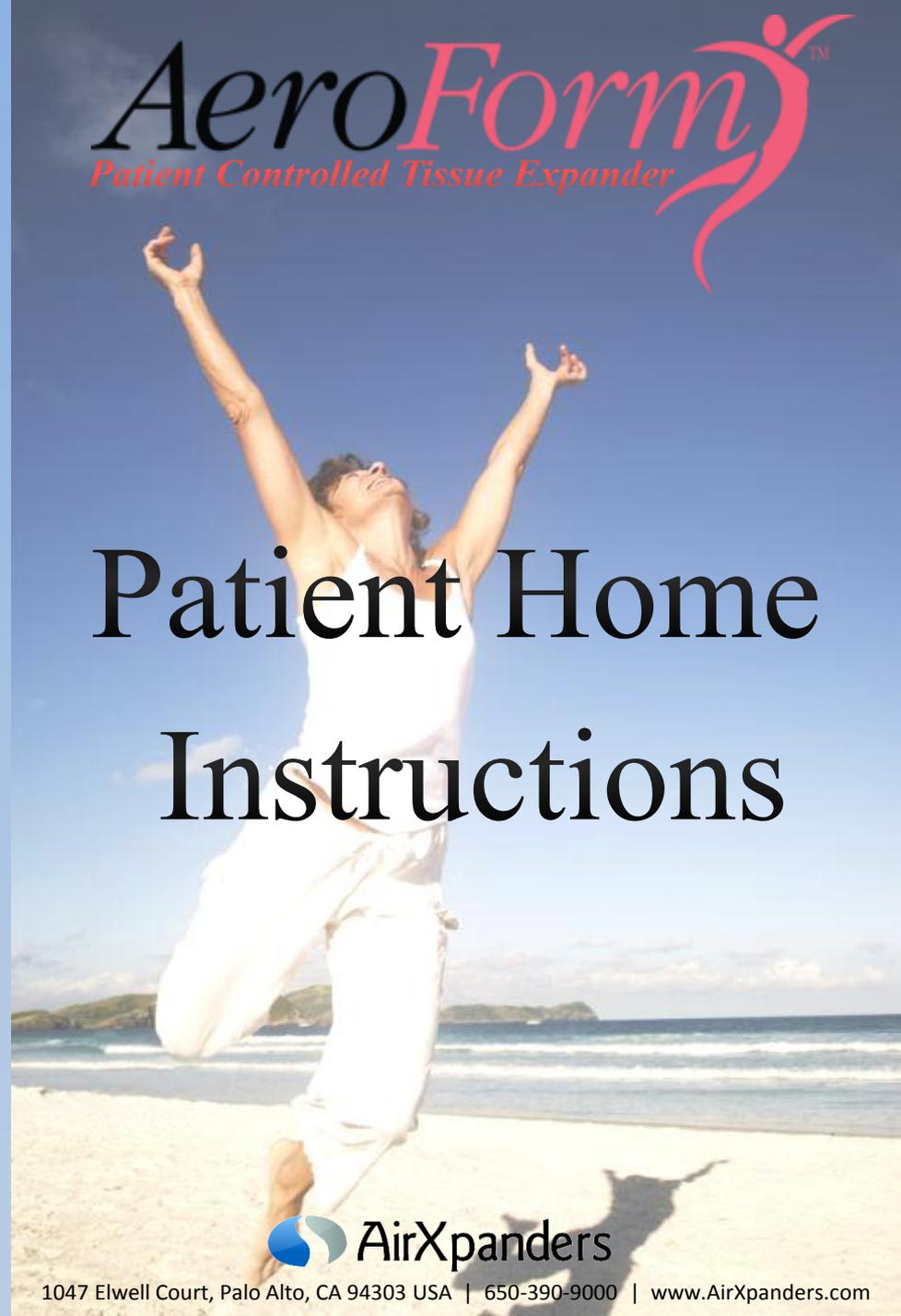
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# Patient Home Instructions



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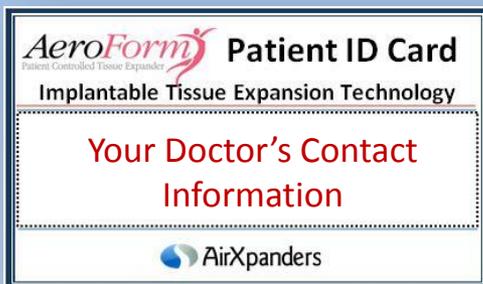
*~ Thank You ~*

For any questions or concerns regarding the tissue expander, call your doctor



## IMPORTANT INFORMATION

- ❑ Call your doctor for any questions or concerns
- ❑ If you are experiencing pain, swelling, redness, oozing or fever, stop dosing and call your doctor
- ❑ If you are experiencing sudden swelling, severe pain, or wound separation, call your doctor immediately
- ❑ If you are in distress and unable to reach your doctor, go to the nearest emergency room
- ❑ Please keep the Patient ID Card with you at all times and present it to medical personnel prior to receiving medical care or when traveling



- ❑ Store your controller in a safe place, away from heat, water and children
- ❑ If the controller is lost or damaged, contact your doctor
- ❑ Your doctor can provide you with a new controller for your existing implant

## USER DIRECTIONS – ONE EXPANDER

The Dosage Controller will be provided by your doctor when you are ready to begin the expansion process

### STEP 1: Turn ON the Dosage Controller



**Press and release**  
the button



5 green lights will  
flash once



You will hear a beep  
and the button will  
stay lit

### STEP 2: Locate Expander with the Dosage Controller

- ❑ Move the controller slowly over the top portion of your breast to detect the expander
- ❑ Look for green lights and listen for a rising tone as the controller gets closer to the expander
- ❑ Once you hear a steady tone and 4-5 green lights appear indicating you are ready to dose, hold the controller in place



Note: The controller automatically turns OFF within 1 minute if the expander is not located

✓ **Ready to Dose**

## STEP 3: Administer a Dose

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**Press and release** the button and **hold** the controller in place until dosing is complete (a few seconds)



### Dosing in Progress...

Look for 1 green light and listen for a steady tone to indicate dosing is in progress



### Dosing is Complete

All 5 green lights will flash and a single tone will sound when dosing is complete



### Controller Turns OFF

The controller will then shut itself OFF

## USER DIRECTIONS – TWO EXPANDERS

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- ❑ Follow ‘User Directions – One Expander’ on pages 2-3
- ❑ If you have two expanders, you should have two (2) controllers, marked Right and Left

## What if the controller can't locate the expander?

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- ❑ Make sure the controller is turned ON
- ❑ Remove bulky/thick clothing and place the controller directly on the skin
- ❑ Try dosing again
- ❑ If the controller still cannot locate the expander, contact your doctor

## Is it possible to over-inflate the expander?

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- ❑ The controller is programmed to prevent you from accidentally adding too much CO<sub>2</sub> to your expander
- ❑ The controller will limit dosing when your expander reaches the full labeled volume

## How do I know when my tissue expansion process is complete?

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- ❑ Your doctor will determine when your tissue is expanded enough to discontinue daily dosing
- ❑ Your doctor may administer or instruct you to administer additional doses to maintain the expander's volume

## What if I moved the controller before dosing was complete?

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You may not receive the full dose.



The controller's lights will flash amber and you will hear a buzzing sound

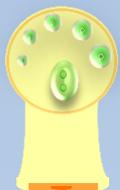
To complete the dose:



Relocate the expander: you should see 4-5 green lights and hear a steady tone



Press and release the button again to restart dosing: you should see one green light and hear a beep



**Hold** the controller **still** until dosing is complete

- Each controller will be able to work with only **one** expander
- Dose one side at a time to ensure proper attention is paid to the light and sound indicators

## DOSING INFORMATION

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The controller is programmed to prevent over-dosing using pre-set limits:

- One dose = 10cc of CO<sub>2</sub>
- Maximum of three (3) doses per day = 30cc total
- Minimum of 3 hours in-between doses
- The controller will stop dosing when the expander is full

If the above limits are reached, the controller will automatically shut OFF

### You may begin daily dosing when:

- Your doctor determines you are ready to begin
- Your surgical incision is healed
- You feel comfortable enough to begin expansion

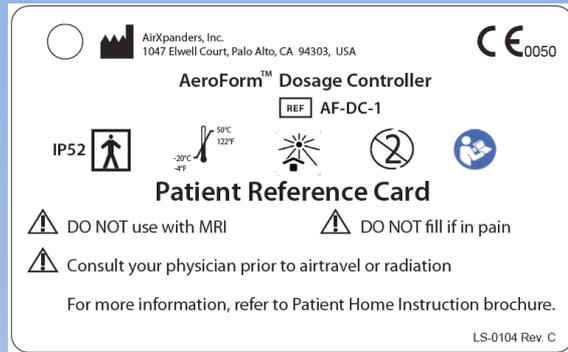
### You may decide how often to dose based on:

- Your comfort level
- Your doctor's direction

Note: There is a limit of 3 doses per day

# PATIENT REFERENCE CARD

A Patient Reference Card is attached to your Dosage Controller. This provides brief instructions and warnings. Please refer to the details below:



Do not reuse



Caution



Review all supplied information prior to use



Device provides protection against electrical shock for medium or long term patient contact



Storage Temperature limitation: -20° C (-4° F) or above 50° C (122° F)



Limited dust and/or liquid protection. Avoid placing device in dusty environments and/or making direct contact with liquids.

# LIMITATIONS

- The expander may activate metal detectors  
*Note: Being scanned by a metal detector will not harm you or the expander*
- You may not receive an AeroForm™ Expander if you have a pacemaker, defibrillator or any other implanted electronic medical device
- Consult your doctor prior to radiation therapy
- DO NOT have an MRI scan while the expander is implanted
- Consult your doctor prior to air travel or ascending more than 1,000 meters (3,300 feet ) while the expander is implanted
- Consult your doctor if you experience any sharp or blunt force injury to the chest area

# FREQUENTLY ASKED QUESTIONS

## What should I do if the Dosage Controller turns OFF during dosing?

- Wait 3 hours** and try dosing again
- If you are still unable to dose, **wait 24 hours** from your first dose that day, and try dosing again
- If you are still unable to dose, contact your doctor