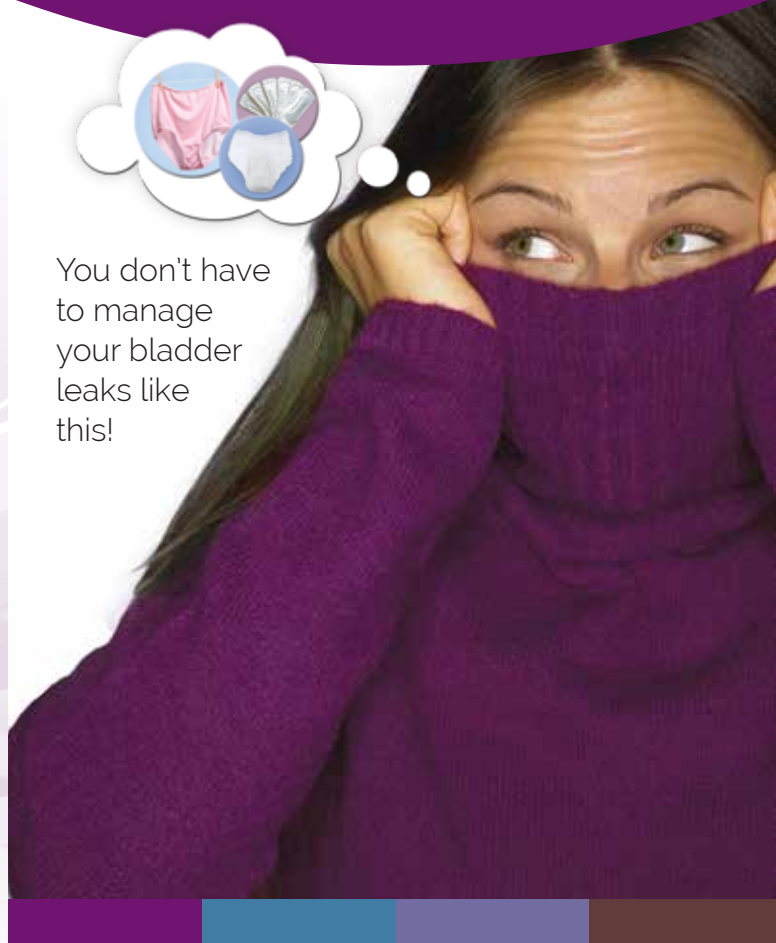


Do you leak urine  
when you laugh, cough,  
sneeze, or exercise?



You don't have  
to manage  
your bladder  
leaks like  
this!



To see if you qualify to participate  
in the **VESICAL Clinical Trial**  
ask your doctor or  
to learn more about the  
**Vesair Bladder Control Procedure**  
visit [www.solacetx.com](http://www.solacetx.com)

What some women who participated in a European  
study said about the Vesair® Bladder Control procedure:

“I am more carefree.”

“No more pads needed, a dry feeling.”

“I can be away from home for longer periods  
and don't need to use any pads anymore.”

“Less worries when I'm  
getting ready to go out.”

#### Privacy:

Study physicians and their staff will respect your privacy. Details about your incontinence symptoms will not be shared with anyone who is not directly associated with the research study. Your study physician will provide you with more specific information on how your personal health information will be treated.

#### References:

<sup>1</sup>NAFC Website: [www.nafc.org/media/statistics/prevalence-2](http://www.nafc.org/media/statistics/prevalence-2)  
Accessed 1/8/2014

<sup>2</sup>Robinson D, Anders K, Cardoza L, et al. "What Women Want – their interpretation of the concept of cure." Abstract presented at ICS August 2002.

<sup>3</sup>The Journal of Urology, Vol. 190 No. 6, 2013. "A Randomized, Controlled Trial of a Novel Intravesical Attenuation Device for the Treatment of Stress Urinary Incontinence."

<sup>4</sup>Neurourology and Urodynamics, Vol. 35 2016. "A randomized, controlled clinical trial of an intravesical pressure-attenuation balloon system for the treatment of stress urinary incontinence in females."

The Vesair Bladder Control System is For Investigational Use Only

AV-1035 Rev. A

A Patient's Guide to:  
Stress Urinary Incontinence  
& the **VESICAL Clinical Trial**

Vesair® Continued Access Trial

## About Stress Urinary Incontinence

Nearly 1 in 3 women ages 18 and older suffer from unexpected bladder leaks - also known as Stress Urinary Incontinence (SUI).<sup>1</sup> This can happen during normal physical activities such as:

- ✔ Laughing
- ✔ Sneezing
- ✔ Coughing
- ✔ Exercise

SUI can greatly diminish a woman's quality of life, and often limits professional, social, sexual, and recreational activities.

SUI occurs when abdominal pressure "pushes" on the bladder during physical activity causing urine to leak. As the illustration below shows, this sudden increase in bladder pressure results in urine loss.



## Current Treatment Options

Patient satisfaction with current treatment options has been limited. In patient studies, women have expressed a desire for a non-surgical option<sup>2</sup>.

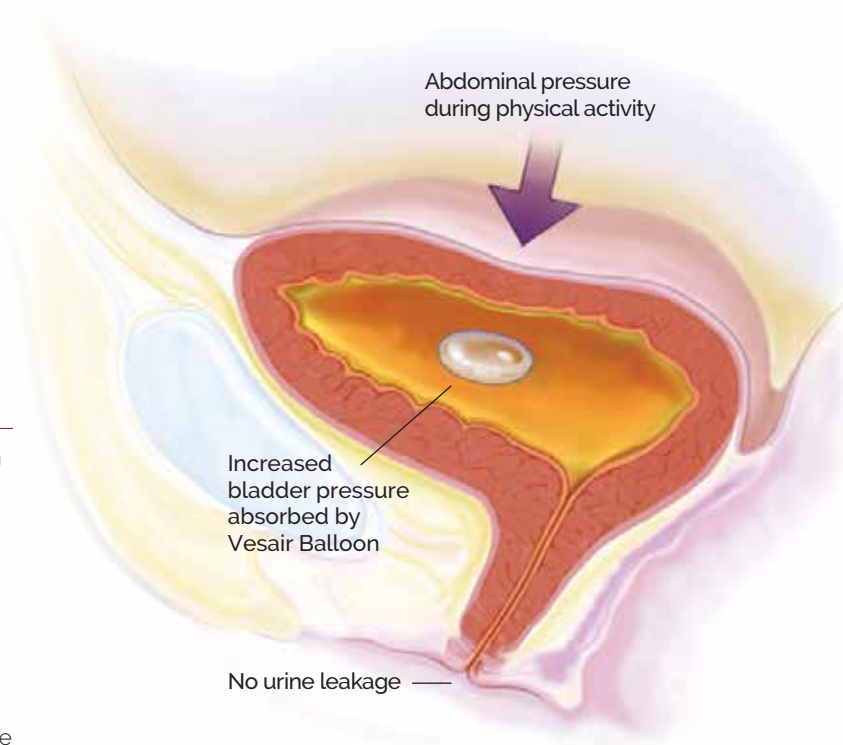
For some women, muscle training exercises (Kegels, biofeedback, etc.) can help improve bladder control during periods of physical stress. However, for those women who respond to this treatment, regular routine exercise is required to provide sustained benefit.

A variety of surgical operations are available to treat SUI. The most common is the sling procedure, in which the middle part of the urethra is surgically supported to reduce urine leakage. Although surgery for SUI can be effective for some women, these procedures can have complications, require general or spinal anesthesia, and require a recovery period.

## About the Vesair<sup>®</sup> Bladder Control Procedure

The Vesair Bladder Control procedure is a novel non-surgical treatment for unexpected bladder leaks and is currently being evaluated in several clinical study locations in the United States.

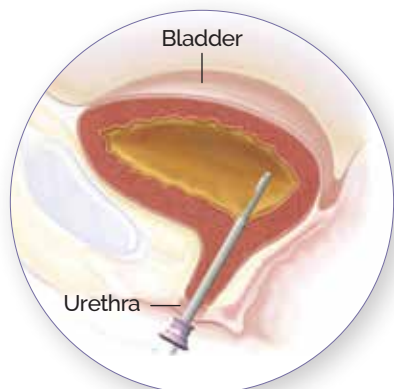
The Vesair Balloon behaves like a "cushion" in the bladder during moments of increased abdominal pressure. The balloon absorbs sudden pressure changes within the bladder, reducing or eliminating urine leakage.



## About the Vesair<sup>®</sup> Bladder Control Procedure

### Vesair Balloon Placement Steps:

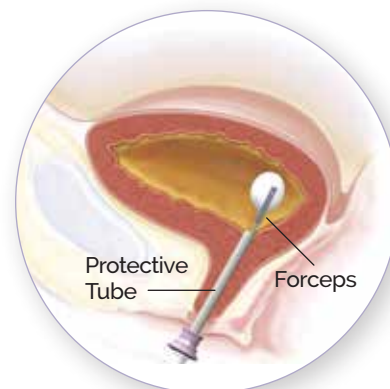
- The Vesair procedure is performed in the doctor's office/ clinic. The Vesair Balloon is inserted into the natural opening of the bladder called the urethra. The need for any pain medication before or after the procedure is rarely required.
- You can resume your normal daily activities immediately following the procedure.
- There are no restrictions or limitations to your lifestyle following the procedure.



A deflated balloon is delivered into the bladder through a protective tube.

### Vesair Balloon Removal Steps:

- The balloon is removed under direct visualization through a protective tube using optical forceps. A new balloon is inserted through the same protective tube. The Vesair Balloon is not a permanent implant and is intended to be replaced annually.
- You are able to resume your normal daily activities after the balloon has been exchanged.



The forceps are inserted into the bladder through a protective tube and grasp the balloon.



The balloon is inflated with air, released, and the protective tube is removed.



The forceps deflate the balloon. The forceps and deflated balloon are removed and a new balloon is inserted.

## About the VESICAL Clinical Trial

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The purpose of this clinical trial is to continue the evaluation of the performance of the Vesair® Bladder Control procedure in post-menopausal women that have Stress Urinary Incontinence (SUI). The **VESICAL Clinical Trial** will follow a carefully controlled protocol (a plan that details what researchers will do during the trial). As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals and to various government agencies. Individual participants' names will remain completely confidential and will not be mentioned in these reports.

If you qualify and choose to join the **VESICAL Clinical Trial**, you will be treated by a trained bladder specialist and will receive all study-related care at no cost. This includes the Vesair Bladder Control procedure, as well as all examinations or visits required for the study. As a participant in the **VESICAL Clinical Trial** you will visit your study doctor's office approximately four (4) times over twelve (12) months to be evaluated and provide feedback about your experience.

To see if you qualify to participate in the **VESICAL Clinical Trial** ask your doctor or to learn more about the Vesair Bladder Control Procedure visit [www.solacetx.com](http://www.solacetx.com)

## Initial Qualification Criteria

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- A willingness to commit to a minimum of 12 months participation
- Post-Menopausal (No menstrual cycle in the previous 12 months).
- History of bladder leaks (SUI) for at least 12 months
- Unsuccessful non-surgical treatment (any one of the following: behavior modification, bladder training exercises, pelvic muscle rehabilitation, biofeedback, electrical or drug therapy)

Participating in any clinical trial is completely voluntary. Your willingness to consider the **VESICAL Clinical Trial** is greatly appreciated and will make a difference in the lives of many women.



## Frequently Asked Questions

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### Has the Vesair® Bladder Control Procedure been studied before now?

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**YES.** The Vesair Bladder Control Procedure has been evaluated in 450 women in three clinical trials in the United States and Europe.<sup>3,4</sup>

- There were no complications that impacted patient's long term health or bladder function.
- Any and all side effects, including urinary tract infection, dysuria, or frequency, were resolved.
- Although rare, some women may require sedation during cystoscopy as they may not tolerate their bladder being distended.
- A majority of the patients reported:
  - An improvement in their incontinence symptoms
  - A reduction in the frequency of their daily leakage events
  - Improvement in their quality of life
  - A reduction in the amount of urine leakage

### What are the potential risks of being in the VESICAL Clinical Trial?

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- Bladder and/or urethral trauma or irritation and/or pain
- Bladder or sphincter muscle spasms
- Urinary symptoms (e.g., urinary tract infection, blood in urine, pain while urinating and urgency to urinate)
- Urethral obstruction
- Stone formation in the bladder
- Abnormalities of the tissue inside the bladder
- Balloon malfunction or deflation
- Although rare, general or local anesthesia or sedation may be required during cystoscopy in instances where a woman cannot tolerate her bladder being filled with fluid

There may be additional risks or side effects that are unknown at this time. Please refer to the Informed Consent for a complete list of potential side effects.

### What will I feel during the Vesair Bladder Control Procedure?

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- Some women felt a brief sensation of pressure, stretching, or slight discomfort.

### What will I feel after the Vesair Bladder Control Procedure?

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- Some women described the feeling of the balloon inside their bladder to be a similar sensation of having a tampon or pessary inside their vagina.
- Some women had mild to moderate bladder irritation that resolved over time, sometimes with medication or dietary changes.
- Some women who experienced irritation that did not resolve within the first 30-45 days post balloon placement had their balloon removed.

### Is there a recovery period?

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**NO.** You can resume your normal daily activities immediately following the procedure. There are no restrictions or limitations to your lifestyle following the Vesair Bladder Control procedure.

### Can I still receive the Vesair Balloon after the first twelve months of the clinical trial?

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**YES.** You can receive the Vesair Balloon for up to an additional two years at no charge. You will still need to complete questionnaires and voiding diaries as required.

<sup>2</sup> The Journal of Urology, Vol. 190 No. 6, 2013. "A Randomized, Controlled Trial of a Novel Intravesical Attenuation Device for the Treatment of Stress Urinary Incontinence."

# Explanation of Questionnaires and Tests

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## What is a Voiding Diary?

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- A paper record of each time you "void" (urinate) and "leak" (unexpected leakage of urine).
- You will be required to complete a diary over a continuous 7-day period, one week prior to each scheduled visit.
- A blank voiding diary will be given to you prior to each visit.
- *The data from your Voiding Diary is essential information that needs to be collected for the purpose of monitoring changes to your voiding habits throughout the duration of the clinical trial.*

## What type of questionnaires will I fill out during each visit?

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The questionnaires used in this study are intended to capture your general health and well-being relative to how your SUI symptoms affect your overall quality of life.

## What is a visual examination of the bladder (Cystoscopy)?

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- The doctor will use a small lighted camera (Cystoscope) to examine the inside of your bladder while at the same time filling the bladder with fluid. A lubricant, with or without a numbing gel, is used to minimize any discomfort. It takes less than 15 minutes to perform. You will be given an antibiotic twice daily for 24 hours before and 24 hours after the cystoscopy to minimize the potential of a urinary tract infection (UTI).

## What is a Bladder Performance Test (Urodynamics)?

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- A test in which your bladder is filled and one small sensor is inserted into the bladder and another into the rectum. Over a period of about 30 minutes, the doctor will measure how well the bladder stores and releases urine. Patients who have this test typically feel no discomfort, but may feel the urge to urinate while the bladder is filled.
- Measurements are taken while sitting/standing.

This test is only performed once during the entire trial period.

## What is a Cough Test?

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- A test that measures urine loss simultaneous with a cough.
- The test will be performed in your doctor's office.
- You will be asked to cough while standing with a full bladder so that the healthcare provider can visually confirm loss of urine during the cough.