

# vSCULPT®

Clinical evaluation of a novel intravaginal device in postpartum women suffering from stress incontinence and sexual function issues.

## THE PROBLEM



**1 in 3 women**

suffer from pelvic floor disorders

### COMMON CAUSES

**Childbirth**  
**Aging**  
**Obesity**

### COMMON SYMPTOMS

**Stress incontinence**  
**Vaginal dryness**  
**Pain with intercourse**



**\$20 Billion**

annual cost to healthcare system



**\$5,600**

annual direct cost to patients

## STUDY DESIGN

Single-site  
Women aged 30-59  
Ob/Gyn Investigator  
Western IRB Approved

Inclusion Criteria:  
Self-reported symptoms of SUI  
Postpartum with 1+ vaginal births  
Pain &/or dissatisfying intercourse

Exclusion Criteria:  
Health-related concerns (STDs, cancer, pregnancy)  
Previous pelvic floor treatments in past 6 months

Protocol:  
24 Self-administered sessions  
10-Min treatments per session  
Sessions every other day for 45 days

Patient Population:  
**48** N=48 Per-Protocol Population  
**38** N=38 Positive PWT at Baseline

MEAN AGE  
**46±7**



## Quality of Life Outcomes **N=48**

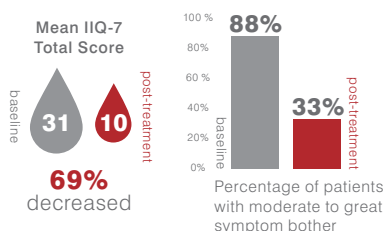
### STRESS INCONTINENCE

#### IIQ-7

**85%**  
of patients improved

#### UDI-6

**92%**  
of patients improved



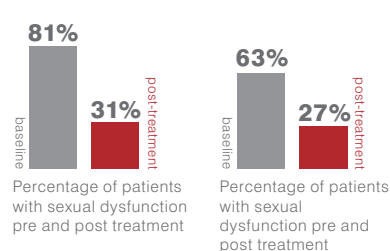
### SEXUAL FUNCTION

#### FSDS-R

**81%**  
of patients improved

#### FSFI

**77%**  
of patients improved



	BASELINE	POST TREATMENT	IMPROVEMENT
UDI-6	<b>53±19</b>	<b>27±10</b>	<b>50%</b>
IIQ-7	<b>31±22</b>	<b>10±11</b>	<b>69%</b>
FSDS-R	<b>21±12</b>	<b>10±10</b>	<b>54%</b>
FSFI	<b>25±6</b>	<b>29±6</b>	<b>15%</b>

Median Scores

## 1 HOUR PAD WEIGHT TEST **N=38**

**90%** of patients improved



Moderate to severe leakage

**82%** → **18%**  
BASELINE POST-TREATMENT

**55%** of women eliminated leakage altogether

## PELVIC FLOOR MUSCLE STRENGTH **N=48**

**82%** improvement



**43%** improved 1 class

**11%** improved 2 classes

## PATIENT SATISFACTION **N=48**



**83%** satisfied with therapy

**95%** patients satisfied amongst those with ≥25% improvement in UDI score

### ADVERSE EVENTS

1 = device too warm  
1 = UTI from improper disinfection

### Legend

PWT	1 hour Pad-Weight Test
SUI	Stress Urinary Incontinence
QoL	Quality of Life questionnaire
IIQ-7	Incontinence Impact Questionnaire
UDI-6	Urogenital Distress Inventory short form
FSDS-R	Female Sexual Distress Scale-Revised
FSFI	Female Sexual Function Index
UTI	Urinary Tract Infection