Physician Care
Clinical Research

# Final Report 02/09/2016

## A Randomized, Double Blind, Crossover Study of the VuVa™ Magnetic Vaginal Dilator Device for Vulvovaginal Pain

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# Table of contents

# Study Synopsis

**Title of study:** A Randomized, Double Blind, Crossover Study of the VuVa™ Magnetic Vaginal Dilator Device for Vulvovaginal Pain

**Publication(s):** None

**Study period:** February 27, 2015 – December 31, 2015

**Objectives:** The primary study outcome is to determine the change in a subject's vestibular pain level as measured by various parameters. Response to treatment will be assessed by subject reported change in pain level using a numeric rating scale during a cotton swab test and tampon test at each office visit. Additionally, patient questionnaires completed at each visit will identify changes in a subject's perception toward vaginal penetration, subject's overall pain intensity when using the device and the frequency of sexual intercourse.

**Methodology:** This was a clinical research trial of up to twenty-four (24) women. Subjects with vulvodynia--vulvar pain at two (2) or more sites tested of at least three (3) or greater on a 0-10 Likert scale, and who had experienced these symptoms for at least three (3) months were eligible to participate in this trial. The study consisted of four (4) sections: a Screening Period during which eligibility was assessed; a Treatment "A" Period of fourteen (14) days; a Washout Period of at least seven (7) days where no treatment was used; and a Treatment "B" Period of fourteen (14) days. Treatment "A" is a fourteen (14) day blinded efficacy and safety assessment period of either the Investigational Device (ID) or the placebo device (standard vaginal dilator). Treatment "B" is a fourteen (14) day blinded efficacy and safety assessment period of the opposite device used during Treatment "A" (e.g. the ID or the placebo device).

The hypothesis is that with appropriate use of the VuVa™ magnetic vaginal dilator device, subjective measurements of pain will be improved as compared with standard non-magnetic vaginal dilators (placebo).

**Number of subjects:**

IRB approved for 24 subjects

12 subjects randomized

10 subjects completed.

## Main criteria for inclusion:

1. Participant must understand and voluntarily sign and date the appropriate Informed Consent document.
2. A female who is ≥ 18 years of age and ≤ 65 years of age.
3. Participant must be able to adhere to the study visit schedule and other protocol requirements.
4. Participant must have vulvodynia--vulvar pain at 2 or more sites tested of at least 3 or greater on a 0-10 Likert scale.
5. Subject-reported vulvar pain for at least 3 months prior to enrollment.
6. Females of childbearing potential (FCBP) must have a negative urine pregnancy test at screening. In addition, sexually active FCBP must agree to use one of the following adequate forms of contraception while in the study: oral, injectable, or implantable hormonal contraceptives; tubal ligation; intrauterine device; barrier contraceptive with spermicide; or vasectomized partner.

**Results:** Subjects were asked to report their pain intensity levels before and after the use of each device.

Tampon Test

Subjects using the VuVa™ magnetic vaginal dilator device reported a decrease in pain levels twice that of placebo (-1.2 vs. -2.6).

Cotton Swab Test

Subjects using the VuVa™ magnetic vaginal dilators experienced an average twenty eight percent (28%) decrease in pain levels.

Vaginal Penetration Cognition

VuVa™ magnetic vaginal dilators proved to be more effective than placebo on subject's sense of control, self-image, optimism, pain levels and genital incompatibility.

Sexual Intercourse

40% of subjects reported an increased frequency in sexual intercourse during the study while using the VuVa™ magnetic vaginal dilators compared with only 10% using placebo.

**Conclusions:** The VuVa™ magnetic vaginal dilator device is a safe and effective treatment of vulvovaginal pain. It performed significantly better than traditional vaginal dilators on standardized pain tests.

**Date of the report:** 02-09-2016

# 1. Introduction

The purpose of this study is to evaluate the safety, efficacy and patient satisfaction of a non-surgical device for vulvar pain. The device is used to treat vulvar pain and related pelvic discomfort. The VuVa™ magnetic vaginal dilator device uses Neodymium magnets within a standard vaginal dilator.

Provoked vestibulodynia, previously called vulvar vestibulitis syndrome, is clinically defined as chronic, unexplained, vulvar pain or discomfort confined to the vulvar vestibule in response to contact or pressure. In addition, many patients also have pain in response to non-sexual activities such as tampon insertion, gynecological examinations or physical pursuits such as bicycle riding; the severity of other vulvo-vaginal symptoms such as itching, burning and irritation varies. Once women with provoked vestibulodynia develop the syndrome, symptoms may last for months or years; as a result, provoked vestibulodynia has a profound effect on women's sexuality and psychological well-being. The diagnosis of provoked vestibulodynia is usually made by ascertaining if the patient fulfills modified Friedrich's criteria, consisting of 1) a history of vulvar pain, dyspareunia or pain with tampon insertion, 2) tenderness of the vestibule when being touched with a cotton-tip applicator and 3) no identifiable cause for the pain.

The etiology of this condition remains unknown. Proposed causes include chronic inflammation, peripheral neuropathy, genetic, immunologic and hormonal factors, infectious, psychological disorders, sexual dysfunction or disturbance in the central nervous system. Because the cause of provoked vestibulodynia remains unknown, many different treatments have been described for this condition, including topical and intra-lesional corticosteroids, topical anesthetics such as lidocaine, topical estrogen, topical or oral antidepressants or anti-convulsants, biofeedback or physical therapy, surgical resection of the involved tissue (vestibulectomy) and a variety of complementary and alternative therapies.

A common non-surgical treatment for vestibulodynia is the use of vaginal dilators. A vaginal dilator is a tube or cylinder made in graduated widths to restore the vaginal opening. Most dilators are made of plastic or rubber, and are used to enlarge or stretch (dilate) the vagina.

The innovation of the VuVa™ magnetic vaginal dilator device is to include the use of Neodymium magnets in the core of the vaginal dilator. The VuVa™ magnetic vaginal dilator device is patent pending with the United States Patent Office. The VuVa™ magnetic vaginal dilator device is a medical grade product manufactured in the United States. Further clinical trials will be considered after completion of this initial study.

Because the VuVa™ magnetic vaginal dilator device is simple innovation over an existing therapeutic device, it has been determined to be a low risk medical device and as such, does not require an Investigational Device Exemption or 510k clearance prior to clinical trial.

# 2. Research objectives

This clinical research study was developed to assist VuVaTech, LLC (the study sponsor) in evaluating the safety and efficacy of the VuVa™ magnetic vaginal dilator device for vulvo-vaginal pain. Additionally, information provided from the study may be helpful to VuVaTech, LLC to the development of their overall marketing strategies.

# 3. Research plan

## Overall study design

The investigators will recruit patients from their private practice. Women 18-65 years of age who have a medical history of vulvar pain and without a known pathologic cause for the vulvar pain are eligible to participate in this trial. Menstruating women must have regular cycles between 25-35 days to be considered eligible to participate in this trial. After the informed consent is obtained and eligibility criteria have been reviewed, the participant's medical history will be obtained and the following screening activities will be completed:

a. Women's health physical including gynecologic exam
b. Urine pregnancy test (Participants will be requested to avoid pregnancy during the eight-week study period by using a reliable contraceptive method. Participants who become pregnant will be withdrawn from the study.)
c. Cotton swab test pain level by verbal reporting.
d. A tampon test.

## Study population

### Patient population

Up to 24 female subjects from Sarasota, Manatee, and Charlotte County in Florida.

### Research inclusion/exclusion criteria

### General Inclusion Criteria for participation in the study

1. Participant must understand and voluntarily sign and date the appropriate Informed Consent document.
2. A female who is ≥ 18 years of age and ≤ 65 years of age.
3. Participant must be able to adhere to the study visit schedule and other protocol requirements.

4. Participant must have vulvodynia--vulvar pain at 2 or more sites tested of at least 3 or greater on a 0-10 Likert scale.
5. Subject-reported vulvar pain for at least 3 months prior to enrollment.
6. Females of childbearing potential (FCBP) must have a negative urine pregnancy test at screening. In addition, sexually active FCBP must agree to use one of the following adequate forms of contraception while in the study: oral, injectable, or implantable hormonal contraceptives; tubal ligation; intrauterine device; barrier contraceptive with spermicide; or vasectomized partner.

## General Exclusion Criteria for participation in the study

1. Pregnant or lactating females.
2. Currently taking narcotics for pain.
3. History of any clinically significant cardiac, endocrine, pulmonary, neurologic, psychiatric, hepatic, renal, hematologic, immunologic conditions, or other major diseases.
4. Any condition which places the subject at unacceptable risk if she were to participate in the study or confounds the ability to interpret data from the study.
5. Use of any investigational medication within 28 days prior to randomization or 5 half-lives if known (whichever is longer).
6. History of malignancy within previous 5 years (except for treated basal-cell skin carcinoma(s) and/or fewer than 3 treated squamous-cell skin carcinomas)
7. History of a vestibulectomy.
8. Currently diagnosed with vulvodynia and receiving treatment.
9. The presence the presence of other vulvar conditions such infection or herpes simplex virus (HSV) upon initial exam.

# 4. Survey instrument amendments, other changes in research

## Survey instrument amendments

Only one amendment was made during the clinical study. The upper age limit on the inclusion criteria was increased from forty (40) years of age to sixty five (65) years of age. This amendment was filed and approved by the IRB. There were no changes made to the study procedures or procedure schedule.

## Other changes in study research

No changes in research conduct occurred during this project.

# 5. Data management

## Data collection

Data was collected at each study visit by the study staff. Subjects were instructed to complete the diary provided.

## Database management and quality control

Data items were directly entered into the database by the research staff. Subsequently, the information entered into the database has not been altered or manipulated in any way. Source documents have been archived and are available for audit if required.

# 6. Research participants

## Demographic and background characteristics

A total of 58 potential subjects were contacted and screened regarding their participation in the study. A total of 12 patients were randomized, with 10 patients completing the entire research protocol.

# 7. Results

The VuVa™ Device Study met its recruitment goal of twelve (12) patients. Even with careful subject selection by the Principal Investigator and the clinical team, two (2) subjects did not complete the study.

## Safety

- None of the study subjects contacted reported any issues or problems with using the device.
- None of the study subjects reported any adverse events when using the device (e.g. pain from the use of the device, discomfort, skin irritation, etc.).
- The two patients that discontinued the study did so for personal reasons (e.g. moving out of the area) that were unrelated to the performance of the device or study design.

## Tampon Test

The tampon test is performed by inserting and immediately removing a tampon and recording the subject's degree of pain during the entire insertion/removal experience on a 0 – 10 pain numeric rating scale with "0" meaning "no pain" and "10" meaning the worst possible pain.

Outcomes specific to the Tampon Test are identified below:

**Tampon Test - Change in Subject Pain Level**

| | Subject Number | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 3 | 4 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | Total |
| **Placebo** | | | | | | | | | | | |
| **Pre-Treatment** | 10 | 9 | 0 | 8 | 10 | 10 | 3 | 8 | 10 | 10 | **7.8** |
| **Post-Treatment** | 10 | 2 | 3 | 6 | 6 | 9 | 3 | 7 | 10 | 10 | **6.6** |
| **Difference** | 0 | -7 | 3 | -2 | -4 | -1 | 0 | -1 | 0 | 0 | **-1.2** |
| **VuVa Device** | | | | | | | | | | | |
| **Pre-Treatment** | 10 | 3 | 6 | 7 | 10 | 10 | 10 | 8 | 9 | 9 | **8.2** |
| **Post-Treatment** | 3 | 2 | 4 | 8 | 10 | 10 | 0 | 6 | 9 | 4 | **5.6** |
| **Difference** | -7 | -1 | -2 | 1 | 0 | 0 | -10 | -2 | 0 | -5 | **-2.6** |
| **Change in Pain Level** | **-7** | **6** | **-5** | **3** | **4** | **1** | **-10** | **-1** | **0** | **-5** | **-1.4** |
| **% Change in Pain Level** | | | | | | | | | | | |
| **Placebo** | 0% | -78% | 300% | -25% | -40% | -10% | 0% | -13% | 0% | 0% | **13%** |
| **VuVa Device** | -70% | -33% | -33% | 14% | 0% | 0% | -100% | -25% | 0% | -56% | **-30%** |

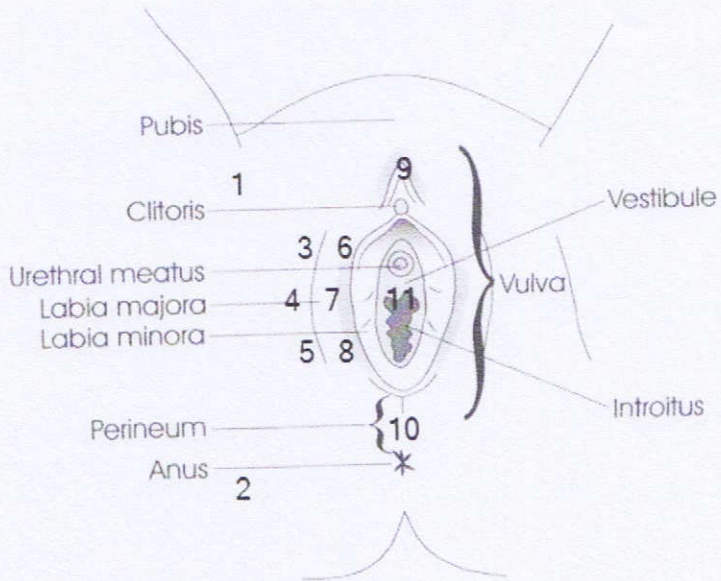
Additional relevant findings are as follows:

- Ninety percent (9 out of 10) of subjects reported a decrease in pain levels using dilators (either the VuVa™ magnetic vaginal dilator device or placebo). This further validates previous research that vaginal dilators can be used for effective treatment of vulvo-vaginal pain.

- Subjects using the VuVa™ magnetic vaginal dilator device reported a decrease in pain levels during the Tampon Test twice than that of placebo (-1.2 vs. -2.6).
- Subjects using the VuVa™ magnetic vaginal dilator device experienced an average of thirty percent (30%) decrease in pain levels on the tampon test.

## Cotton Swab Test

The cotton swab test is a non-invasive test used to assess complaints of vaginal pain. This test is performed using a cotton swab with which gentle pressure is applied in a circular fashion around specific areas of the vulvar vestibule. Subjects were tested before and after use of a device. A total of eleven (11) sites were evaluated and a pain score between 0 - 10 at each site was verbally reported by each subject. Subjects were tested before and after use of a device.




Outcomes specific to the Cotton Swab Test are identified below:

**Total Number of Sites Where Pain was Reported**

| | Subject Number | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Placebo** | **1** | **3** | **4** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **Total** |
| **Decreased Number of Sites** | | x | | | | x | | | | | 2 |
| **No Change in Number of Sites** | x | | | x | x | | | | x | x | 5 |
| **Increased Number of Sites** | | | x | | | | x | x | | | 3 |

| | Subject Number | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **VuVa Device** | **1** | **3** | **4** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **Total** |
| **Decreased Number of Sites** | x | x | x | x | x | x | x | | | x | 8 |
| **No Change in Number of Sites** | | | | | | | | x | x | | 2 |
| **Increased Number of Sites** | | | | | | | | | | | 0 |

**Number of Sites Where Subjects Reported Pain**

| | Subject Number | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **1** | **3** | **4** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **Total** |
| **Placebo** | | | | | | | | | | | |
| **Pre-Treatment** | 2 | 4 | 2 | 6 | 5 | 12 | 6 | 6 | 7 | 7 | **5.7** |
| **Post-Treatment** | 2 | 3 | 5 | 6 | 5 | 10 | 7 | 10 | 7 | 7 | **6.2** |
| **Difference** | 0 | -1 | 3 | 0 | 0 | -2 | 1 | 4 | 0 | 0 | **0.5** |
| **VuVa Device** | | | | | | | | | | | |
| **Pre-Treatment** | 5 | 2 | 4 | 6 | 8 | 9 | 6 | 9 | 6 | 7 | **6.2** |
| **Post-Treatment** | 1 | 1 | 1 | 4 | 3 | 7 | 4 | 9 | 6 | 3 | **3.9** |
| **Difference** | -4 | -1 | -3 | -2 | -5 | -2 | -2 | 0 | 0 | -4 | **-2.3** |
| | | | | | | | | | | | |
| **% Change** | | | | | | | | | | | |
| **Placebo** | 0% | -25% | 150% | 0% | 0% | -17% | 17% | 67% | 0% | 0% | **19%** |
| **VuVa Device** | -80% | -50% | -75% | -33% | -63% | -22% | -33% | 0% | 0% | -57% | **-41%** |

**Average Change in Pain Level**

| | Subject Number | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **1** | **3** | **4** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **Total** |
| **Placebo** | | | | | | | | | | | |
| **Pre-Treatment** | 1.09 | 1.91 | 0.18 | 2.18 | 2.64 | 8.36 | 1.27 | 3.64 | 3.91 | 2.82 | **2.8** |
| **Post-Treatment** | 1.09 | 1.18 | 1.73 | 2.55 | 1.55 | 4.91 | 1.82 | 5.64 | 3.91 | 3.27 | **2.765** |
| **Difference** | 0 | -0.73 | 1.55 | 0.37 | -1.09 | -3.45 | 0.55 | 2 | 0 | 0.45 | **-0.035** |
| | | | | | | | | | **Total Change in Pain Level** | | -1% |
| **VuVa Device** | | | | | | | | | | | |
| **Pre-Treatment** | 1.91 | 0.55 | 0.82 | 2.00 | 3.64 | 3.64 | 2.09 | 4.82 | 3.09 | 3.55 | **2.611** |
| **Post-Treatment** | 0.27 | 0.09 | 0.09 | 1.64 | 0.73 | 5.73 | 1 | 6.64 | 2.05 | 0.64 | **1.888** |
| **Difference** | -1.64 | -0.46 | -0.73 | -0.36 | -2.91 | 2.09 | -1.09 | 1.82 | -1.04 | -2.91 | **-0.723** |
| | | | | | | | | | **Total Change in Pain Level** | | -28% |
| **% Change** | | | | | | | | | | | |
| **Placebo** | 0% | -38% | 861% | 17% | -41% | -41% | 43% | 55% | 0% | 16% | **87%** |
| **VuVa Device** | -86% | -84% | -89% | -18% | -80% | 57% | -52% | 38% | -34% | -82% | **-43%** |

Additional relevant findings are as follows:

- Eighty percent (80%) of study subjects reported a decrease in overall pain after using the VuVa™ magnetic vaginal dilators.

- The cotton swab test evaluates eleven (11) different locations of the vulvar vestibule for pain. Eighty percent (80%) of the study subjects reported a decrease in the total number of locations after using the VuVa™ magnetic vaginal dilators.

- Subjects using the VuVa™ magnetic vaginal dilators experienced an average twenty-eight percent (28%) decrease in pain levels using a standardized cotton swab test, which is a non-invasive measure of vaginal pain.

## Vaginal Penetration Cognition Questionnaire

Patients diagnosed with Vulvodynia experience pain that can interfere with all aspects of sexual functioning. Patients commonly describe a persistent and distressing difficulty in vaginal insertion of a penis, finger, tampon, or other object. This recurrent and persistent genital pain associated with sexual intercourse causes significant personal distress.

The currently prominent cognitive–behavioral approach to the sexual pain disorders hypothesizes that maladaptive cognitions, such as catastrophic beliefs, underlie the fear response to certain sexual penetration stimuli. For example, it is assumed that fear of penetration is maintained through the reinforcing effect of avoidance behavior on erroneous cognitions, as avoidance and escape of phobic objects and activities preclude opportunities to disconfirm anxiety-inducing beliefs (e.g., "Penetration is impossible, it will not fit, it will elicit unbearable pain"). It is also assumed that catastrophic pain cognitions (e.g., "it will always cause pain, this pain will be intolerable") are activated by the prospect of painful intercourse, resulting in vaginal dryness and/or increased pelvic floor muscle tone. This reaction subsequently causes friction between the penis and the vulvar skin, which may result in increased/enhanced pain. As a result, cognitive–behavioral interventions often include some form of fear reduction exercises (e.g. exposure, cognitive restructuring) and pain management techniques.

The Vaginal Penetration Cognition Questionnaire consists of forty (40) questions that are scored on a scale of zero ("0") to six ("6") with zero being "Not at all applicable" and six being "Very strongly applicable".

The questions are designed to provide insights on a subject's perception in five areas:

a. Control – does the subject feel in control of their sexual well-being
b. Pain – the pain levels associated with sexual intercourse and the ability to manage it
c. Self-image - the patient's image of themselves related to sexual intercourse
d. Optimism – positive feelings that sexual intercourse may be possible or will be better in the future
e. Genital incompatibility – the subject's view of their genital make up and physical structure

Women diagnosed with vulvodynia who have completed the questionnaire have reported lower levels of control, self-image and optimism, and higher levels of pain and genital incompatibility.

The purpose of including the Vaginal Penetration Cognition Questionnaire in this clinical trial was to determine if the VuVa™ magnetic vaginal dilators had any effect on the subject's sexuality and psychological well-being when compare with placebo.

All subject's reported improvements in their sense of control, self-image and optimism from baseline (before any treatment) throughout the study, regardless of the order in which they used the VuVa™ magnetic vaginal dilators or placebo.

Pain levels and genital incompatibility also showed improvement over baseline.

This finding also further validates that standard vaginal dilator therapy can have a positive effect on a woman's sexuality and psychological well-being.

Additionally, the VuVa™ magnetic vaginal dilators proved to be more effective than placebo on subject's sense of control, self-image and optimism. Specific examples include:

| **Question #35: My mind says "yes", but my body says "no" to penetration.** | | |
|---|---|---|
| | **VuVa™** | **Placebo** |
| **Average Score (0-6)**<br>0 = Not at all applicable<br>6 = Very strongly applicable | 4.00 | 4.67 |

| **Question #11: I am only a complete woman when penetration is successful.** | | |
|---|---|---|
| | **VuVa™** | **Placebo** |
| **Average Score (0-6)**<br>0 = Not at all applicable<br>6 = Very strongly applicable | 2.00 | 3.10 |

| **Question #20: I will be able to have a sex life that includes penetration in the future.** | | |
|---|---|---|
| | **VuVa™** | **Placebo** |
| **Average Score (0-6)**<br>0 = Not at all applicable<br>6 = Very strongly applicable | 4.00 | 2.78 |

VuVa™ magnetic vaginal dilators also proved to be more effective than placebo on questions pertaining to pain levels and genital incompatibility. Specific examples include:

| **Question #37: Penetration will not be painful for me.** | | |
|---|---|---|
| | **VuVa™** | **Placebo** |
| **Average Score (0-6)**<br>0 = Not at all applicable<br>6 = Very strongly applicable | 2.78 | 0.89 |

| **Question #1: I am afraid that my vagina is too narrow for penetration.** | | |
|---|---|---|
| | **VuVa™** | **Placebo** |
| **Average Score (0-6)**<br>0 = Not at all applicable<br>6 = Very strongly applicable | 1.30 | 2.30 |

## Sexual Intercourse Diary

Subjects were asked to keep a daily diary to record their sexual intercourse activity throughout the study. Subjects recorded each day if they had sexual intercourse in the past 24 hours and provided additional information as follows:

| **Sexual Intercourse in the past 24 hours** | | | | **Pain Level During Intercourse (0-10)** |
|---|---|---|---|---|
| **No, too painful** | **No, not interested** | **No, no opportunity** | **Yes** | **(0 = no pain)**<br>**(10 = worst pain possible)** |

Results from analysis of the sexual intercourse diaries were as follows:

- Fifty percent (50%) of the study subjects did not have any sexual intercourse during the study
- Of those that did engage in sexual intercourse, eighty percent (80%) reported an increase frequency in sexual intercourse while using the VuVa™ magnetic vaginal dilators.

# 8. Overall conclusions

## Conclusions

The VuVa™ magnetic vaginal dilator device is a safe and effective treatment for vulvovaginal pain and related pelvic discomfort. The VuVa™ magnetic vaginal dilator device is easy for users to understand and function, and will not cause harm to users.

The VuVa™ magnetic vaginal dilator device was more than twice as effective in reducing vulvovaginal pain and related pelvic discomfort when compared with placebo (standard vaginal dilators) during a standardized Tampon Test. Subjects using the VuVa™ magnetic vaginal dilators experienced an average twenty-eight percent (28%) decrease in pain levels when scored using a standardized Cotton Swab Test.

Subjects experienced an overall increase in their psychological well-being when using the VuVa™ magnetic vaginal dilators. This was assessed using the Vaginal Penetration Cognition which evaluates five specific psychological components including control, pain, self-image, optimism and genital incompatibility.

And forty percent (40%) of the study subjects reported an increase in the frequency of sexual intercourse while using the VuVa™ magnetic vaginal dilators compared with only ten percent (10%) using placebo.

Comments about the VuVa™ magnetic vaginal dilator device from research subjects include:

> "I normally use tampons through the course of my cycle and always feel an irritating abrasion-like discomfort when inserting and removing a tampon, I didn't feel it with this cycle or when using dilators."
>
> "I want the other set! I felt differently with the first set, and feel there is definitely a possibility of pain free intercourse!"
>
> "I would like to keep these!! I think it would be great to use these before intercourse to "ease" the way."
>
> "The last size of the dilator used made me feel a "light tingle" and I noticed lasting results (no pain throughout the day and more lubrication)."
>
> "This set of dilators felt like they actually did something, not like the ones before."
>
> "There is no pain when inserting the dilators. This is probably due to the smooth, sleek surface of the dilator."
>
> "I am almost pain free since using the dilators 7 days ago."