

NuGyn™ Eros Therapy™ — An Effective Therapy for Female Sexual Dysfunction

a report by

NuGyn Inc.

Introduction

Female sexual dysfunction (FSD) is a medical condition that has received little attention in the past. Now, with an increased awareness of women's health issues, FSD is being discussed more openly. In addition, availability of both old and new treatments for male erectile dysfunction has prompted women to demand effective solutions for their own sexual concerns. In fact, sexual dysfunction is actually more prevalent in women than men. More than 43% of American women (about 40 million) experience some form of sexual disorder.

Few treatments have been available for the treatment of FSD. The medical community is now beginning to address FSD from the perspective that some aspects of FSD are likely to be caused in part by decreased blood flow to the genitalia. Poor genital blood flow is believed to contribute to female arousal or orgasm disorders similar to the role of vascular disease in male erectile dysfunction. During female sexual stimulation, peripheral genital arousal results in increased blood flow and tissue pressure within the clitoris. This physiologic clitoral engorgement is believed to enhance sexual function by increasing clitoral sensation, vaginal lubrication, orgasmic response and overall sexual satisfaction.

NuGyn's Eros Therapy device is the only available, clinically proven product cleared by the US Food and Drug Administration (FDA) for women who suffer from FSD of an organic nature, specifically arousal and orgasmic disorders. The Eros Therapy device was cleared-to-market by the FDA in April 2000, as the first device for treatment of FSD. NuGyn's Eros Therapy device is a hand-held, battery-operated, non-invasive, non-pharmacological treatment designed to increase blood flow to the genitalia by creating a gentle suction around the clitoris. When the device is placed over the clitoris and the pump is activated, a vacuum is created that draws blood into the clitoris, causing clitoral and then vaginal engorgement, leading to increased vaginal lubrication, and the foundation is laid for the orgasmic experience.

NuGyn's Eros Therapy Device

NuGyn's Eros Therapy device is a non-invasive, small, hand-held medical device that improves sexual responses by increasing blood flow to the clitoris and external genitalia. It is lightweight, easy to use and available only by a doctor's prescription. When the Eros Therapy device is switched on, a gentle vacuum is created causing clitoral engorgement and increasing blood flow to the genital area.

The device consists of a battery-operated vacuum pump, connecting tubing, and a disposable vacuum cup. The CAREss™ Cup is placed over the clitoris. An on/off switch on the side of the device activates the pump to create a vacuum. The vacuum draws blood into the clitoris causing tumescence. On the opposite side of the device is a variable leak roller wheel and modulation control that allows the patient to control the desired amount and pulsation of vacuum level.

The Eros Therapy device is used in the privacy of the patient's home and should be used four to seven times per week to achieve the maximum benefit that NuGyn Eros Therapy offers. A woman may use the device either prior to having intercourse or therapeutically without intercourse. Eros Therapy may be considered a conditioning routine to restore blood flow to the clitoris and genitalia, and to increase overall sexual satisfaction. Numerous clinical studies have proven that Eros Therapy is safe and effective for women with FSD. There are no reported side effects when the Eros Therapy device is used as directed.

Response to Eros Therapy

NuGyn's Eros Therapy device is designed to increase blood flow in the clitoris to assist a woman to achieve engorgement of the clitoral cavernosal tissue. The mechanism of clitoral engorgement is similar to that of the male vacuum erection device, which causes penile blood flow engorgement in the cavernosal tissue. The NuGyn Eros Therapy device is intended for use as a therapy for women with female sexual arousal disorders including diminished vaginal lubrication, diminished

Figure 1: NuGyn Eros Therapy Device

clitoral sensation, lowered sexual satisfaction and a reduced ability to achieve orgasm.

This increase in blood flow from Eros Therapy results in:

- greater clitoral and genital sensitivity;
- improved lubrication;
- enhanced ability to achieve orgasm; and
- increased overall sexual satisfaction.

It is important that the device is used as described in the instruction manual that comes with the product. It may take several weeks to realize the therapeutic benefits of using the Eros Therapy device although some women may begin to notice changes quickly.

NuGyn Eros Therapy

The Eros Therapy device is clinically proven and indicated for women with arousal and orgasmic disorders. Certain physical conditions, which cause constriction of the vaginal and clitoral arteries, may interfere with, or prevent a woman from, achieving clitoral tumescence. It is believed that the difficulty or inability to achieve clitoral tumescence may be related to other symptoms of FSD such as lack of desire, difficulty achieving orgasm, insufficient vaginal lubrication, and painful intercourse.

It is generally accepted that clitoral stimulation and tumescence are important aspects of female sexual arousal. Tumescence, or engorgement, occurs when the

clitoris fills with blood. The female clitoris is a homologue of the male penis and the erectile process is very similar in each organ. FSD due to diminished blood flow to the genitalia may result from common medical conditions. These conditions include menopause, diabetes, cardiovascular disease (CVD), smoking, and many other conditions that affect normal blood flow. New paradigms in hormonal treatment for peri-menopausal and post-menopausal women may also lead to greater incidence of vaginal dryness that is treatable by Eros Therapy.

Arousal and orgasmic disorders can be caused by a lack of blood circulation to the clitoris and genital area and may be related to medical conditions such as:

- menopause;
- vascular disease;
- high blood pressure;
- diabetes; and
- smoking.

Patient Education about Female Sexual Health

Despite the common occurrence of FSD, many women may be too embarrassed or reluctant to discuss their sexual problems with their physician. In addition, physicians have had few effective treatments to prescribe for FSD. NuGyn Eros Therapy gives the physician the opportunity to prescribe an effective treatment for patients who complain of diminished vaginal lubrication, decreased clitoral sensitivity, lowered ability to achieve orgasm, or reduced overall sexual satisfaction.

With more treatments available for male erectile dysfunction and tremendous marketing resources being expended in this area, there is now greatly increased awareness of sexual health. Women are clearly an important part of the sexual health equation and they often question why greater attention has not been centered on development of effective treatments for their sexual disorders. NuGyn, Inc. is a healthcare company that has developed and clinically proven NuGyn Eros Therapy to be an effective treatment to improve women's sexual health.

Educational resource materials are available online¹ for information about sexual health. An online quiz is also available for patients.² This quiz is designed to provide answers to questions that are useful for a physician to evaluate the symptoms and potentially the source of a woman's sexual health problems. The online quiz was created for women who suspect they may have FSD. It was developed by Dr Kevin Billups a board certified

1. www.eros-therapy.com

2. <http://www.nugyn.com/quiz.cfm>

urologist specializing in male and female sexual health; Dr Philip Sarrel a board-certified gynecologist specializing in menopause and aging issues; and Dr Maryann Schroder, a board-certified clinical sexologist and certified family nurse practitioner specializing in women's sexual health. This quiz is not intended to be a substitute for professional medical advice or a medical diagnosis but as a tool to initiate communication between patients and their healthcare provider regarding questions they may have about FSD.

Conclusion

NuGyn's Eros Therapy device has been clinically proven to be a safe and effective treatment for women with female sexual arousal disorders including

diminished vaginal lubrication, diminished clitoral sensation, lowered sexual satisfaction and a reduced ability to achieve orgasm. This treatment provides physicians with an important option for patients who suffer from the symptoms of poor sexual health. ■

Contact Information

For more information, including clinical studies, information and sexual health concern discussions, visit:

Website: <http://www.eros-therapy.com>