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Valayza™ Informed Consent Agreement 2018

Patient Name: _____ Date: _____

DOB: _____

Introduction

The following is an informed consent document. Please read it carefully. It does not take the place of a conversation with the doctor regarding this proposed procedure. This document is intended to help provide information that a patient needs to have to make an informed decision about a particular medical procedure, in this case, the Valayza™ Procedure (vaginal laser using the Mona Lisa Touch device).

Full Disclosure

Please carefully read the following paragraphs regarding concerns voiced by the FDA and by ACOG (American College of Ob/Gyn) as well as our own response. Copies of the complete articles are available upon request.

Risks of the procedure – FDA Issues Safety Alert and Press Release[1]

Risks from this procedure have been reported. On July 30, 2018, the FDA issued a "Safety Alert[2]" on the use of a vaginal laser for "vaginal rejuvenation" or for treatment of menopausal-related vaginal conditions. They warned that they "found numerous cases of vaginal burns, scarring, pain during sexual intercourse, and recurring or chronic pain" but they do not report the percentages of these risks.

They state that "the FDA has cleared or approved laser and energy-based devices for the treatment of serious conditions like the destruction of abnormal or pre-cancerous cervical or vaginal tissue, as well as condylomas (genital warts). But the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for "vaginal rejuvenation." Therefore, the vaginal laser is deemed safe by the FDA for other vaginal conditions but is not specifically approved by the FDA for the treatment of post-menopausal vaginal atrophy.

The FDA stated that "The deceptive marketing of unproven treatments may not only cause injuries but may also keep some patients from accessing appropriate, recognized therapies to treat severe medical conditions. These products may be particularly appealing to women who may not be candidates for certain FDA-approved treatments to relieve vaginal dryness, and thus are seeking alternative, nonhormonal options. Women considering treatment for vaginal symptoms should speak to their doctor about the potential and known benefits and risks of all available treatment options."

The FDA has not banned the vaginal laser for treatment of post-menopausal vaginal atrophy. They are focusing on the "deceptive marketing" of the laser by the laser manufacturers who are implying that the laser is "approved" for this type of treatment which it isn't. The FDA specifically requests that patients speak to their doctor about risks, benefits and all available treatment options and we agree completely with this.

Here is an excerpt from a letter we received from Hologic , the owner of CynoSure which is the US distributor of the Mona Lisa Touch Laser: "The letter received by Hologic did not question the safety of the device but did question some of the claims located on our website and whether our existing 510(k) clearances adequately include those claims."

Initials indicate this was read and understood _____

American College of Ob/Gyn Position Statement (ACOG)

Here are excerpts from the ACOG Position Statement[3]:

"The purpose of this Position Statement is to advise obstetrician–gynecologists and patients that this technology is, in fact, neither approved nor cleared by the FDA for the specific indication of treating vulvovaginal atrophy. Although initial data indicate potential utility, additional data clearly are needed to further assess the efficacy and safety of this procedure in treating vulvovaginal atrophy, particularly for long-term benefit."

"It is critical that patients are provided with accurate information regarding the efficacy and safety of treatment options, particularly when considering emerging technology. One component of this information is an accurate description of the FDA's clearance or approval terminology. Obstetrician–gynecologists have an ethical responsibility to provide accurate and current information to patients in order for them to be fully engaged in the informed decision-making process."

WE AGREE 100% WITH THE ACOG STATEMENT.

Initials indicate this was read and understood _____

Fair Oaks Women's Health Statement

We have published on our web site our comments about the FDA warnings[4]. We feel strongly that this procedure is safe and effective for the treatment of post-menopausal vaginal atrophy. Numerous published peer-reviewed articles have shown this to be true. There is no such thing as a risk-free treatment and this is as true for vaginal laser as it is for other medical treatments and procedures. Because this is not an FDA approved treatment, it is referred to as an off-label treatment. Patients have the right to make their own decisions after being properly informed about the nature of the proposed treatment, and the risks, benefits, side effects and alternatives.

Initials indicate this was read and understood _____

Explanation of the Procedure

The Valayza™ Procedure involves the use of an intravaginal laser called the MonaLisa Touch™. Numerous peer-reviewed studies have shown this procedure to be a safe and effective treatment for vaginal atrophy, a condition that can cause vaginal dryness, burning, itching, discomfort, urinary urgency and painful intercourse.

After a vaginal examination and preparation, a special wand, similar to what is used for a vaginal ultrasound, is inserted into the vagina. The procedure is performed by either a gyn physician or an RN trained and certified to perform the procedure. Eye protection devices will be used.

Once the wand is in place, brief laser pulses are created which cause a brief flash of light and heat inside the vagina. There might be a tingling sensation inside the vagina which gets a little stronger near the vaginal opening, and there might be small puffs of air felt inside the vagina during the procedure. There may be an odor of heated tissue.

The wand is pulled a short distance out and the pulses are repeated. This continues until the length of the vagina has been treated, then the wand is removed. The treatment generally lasts just a few minutes.

Benefits of the Valayza™ Procedure – the three R's (renew, restore, revive !)

The laser causes thermal stimulation and microscopic tissue damage to the vaginal walls (the vaginal mucosa or mucous membrane). The body responds to this with a significant healing reaction. This healing reaction thickens and renews the vaginal wall. The thicker vaginal wall helps restore the vagina to a moist, lubricated, pre-menopausal state, without the use of estrogen. Three treatments are advised for optimal benefit and then one treatment about every 12 months to maintain. Women should be prepared to experience increased vaginal sensation and pleasure during sex following each treatment. Vaginal lubrication may improve and orgasms may become more intense (revive your sex life!)

Side Effects

Side effects include a feeling of heat or warmth during and after the procedure which at times can be uncomfortable and normally is brief, but can last a few days or more. There might be some watery vaginal discharge or light spotting as part of the healing response, but heavy bleeding is not expected. Sex should be abstained from for about 2-3 days after the treatment, and do not use tampons during this time as well.

Initials indicate this was read and understood _____

Call the doctor if:

As with any medical procedure, there is no guarantee as to the results, and possible complications can occur. Therefore, if you experience fever (higher than 100.5 degrees), severe vaginal pain, moderate vaginal bleeding (more than staining or spotting) or a foul smelling vaginal discharge, please call the doctor's office immediately.

Initials indicate this was read and understood _____

After-care Instructions

I have received the handout describing aftercare instructions. I have reviewed these instructions and plan to follow them.

Initials indicate this was read and understood _____

Consent for Procedure and Treatment:

I have read all the above information and I understand it. I understand what the FDA's concerns are. I am aware that using the vaginal laser to treat vaginal atrophy is considered off-label. All my questions have been answered to my satisfaction. By signing below, I consent to having a Valayza™ Procedure and I consent to this and all future Valayza™ Procedures. I may cancel my consent in writing at any time.

I have been informed that I might experience one or more of the complications and/or side effects listed above under the Risks section. I understand the risks and benefits of the Valayza™ Procedure and I accept these risks. I agree to follow all the aftercare instructions and to call the doctor right away if I experience any of the problems mentioned above or if I experience any unusual symptoms that might be related to having done this procedure.

I understand that there is no guarantee regarding the results or outcome of the Valayza™ Procedure.

Patient Name: _____

Patient Signature: _____ Date Signed: _____

[1] Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation". July 30, 2018. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm

[2] FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication. www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm615013.htm

[3] Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance Position Statement.

www.acog.org/Clinical-Guidance-and-Publications/Position-Statements/Fractional-Laser-Treatment-of-Vulvovaginal-Atrophy-and-US-Food-and-Drug-Administration-Clearance. May 2016, reaffirmed July 2018.

[4] Fair Oaks Women's Health online published statement. www.fowh.com/FDA_Update.html

PEER REVIEWED PUBLISHED STUDIES (partial list)

Salvatore S, Digesu G, Siesto G, et al. Vaginal collagen remodelling after fractional carbon dioxide laser surgery [abstract 233]. Presented at Annual Meeting of the International Continence Society, Glasgow, United Kingdom, August – September 2011.

S. Salvatore et al. A 12-week treatment with fractional CO2 laser for vulvovaginal atrophy: a pilot study. Climacteric Aug 2014, Vol. 17, No. 4: 363–369.

N. Zerbinati et al. Microscopic and ultrastructural modifications of postmenopausal atrophic vaginal mucosa after fractional carbon dioxide laser treatment. Lasers Med Sci (2015) 30:429–436.

S. Salvatore et al. Sexual function after fractional microablative CO2 laser in women with vulvovaginal atrophy. Climacteric 2014 Oct 21:1-21.

Karram M and Sokol E. A new and novel therapy for vulvovaginal atrophy: results of the first U.S. trial. Presented at 2014 Pelvic Anatomy and Gynecologic Surgery Symposium (PAGS), Las Vegas, NV.

Stefano Salvatore, MD, et al. Histological study on the effects of microablative fractional CO2 laser on atrophic vaginal tissue: an ex vivo study. Menopause: The Journal of The North American Menopause Society.Vol. 22, No. 8, pp. 845/849.

J. Hutchinson-Colas, S. Segal, Genitourinary syndrome of menopause and the use of laser therapy, Maturitas. 2015, Volume 82, Issue 4, Pages 342–345. http://dx.doi.org/10.1016/j.maturitas.2015.08.001

Santiago Palaciosa, et al. Update on management of genitourinary syndrome of menopause: A practical guide. Maturitas 82 (2015) 307–312. http://dx.doi.org/10.1016/j.maturitas.2015.07.020