



# ACADEMIA

OF WOMEN'S HEALTH &  
ENDOSCOPIC SURGERY

Dear Patient:

I am writing you in response to the recent publicity surrounding the Mona Lisa Touch Laser (the “MLTL”) because we treated you with the MLTL procedure at our practice. Specifically, the U.S. Food and Drug Administration (“FDA”) has issued a statement about *advertising* the MLTL, and similar energy based medical devices, as an effective method to treat symptoms related to menopause, urinary incontinence, or sexual function, through (i) vaginal rejuvenation, (ii) cosmetic vaginal procedures, and (iii) non-surgical vaginal procedures. The FDA has yet to confirm the safety and effectiveness of energy-based medical devices specifically for the above-referenced procedures, and therefore, has not approved the advertising of these lasers for treating the above-referenced symptoms.

The purpose of this letter is to put your mind at ease regarding Academia’s use of MLTL treatment relative to the FDA’s concerns. As you know, I approach medical conditions conservatively, and only employ treatment methods with scientific studies which support scientifically-proven benefits. I had an early opportunity to learn about, and work with, the MLTL in Russia, and I have conducted numerous tests with the device which support the mode and purpose for its use in my practice. For example:

1. We do not use - nor advertise the use of - the MLTL for vaginal “rejuvenation purposes.” Instead, we treat conditions, including vaginal atrophy, with associated discomfort or vaginitis. While the FDA states that the effectiveness of the MLTL for vaginal atrophy “has not been established”, we have had great success with its use in our practice with no complications.
2. We recognize that each patient is different, and therefore, understand that the potential negative side effects that could result from use of the MLTL along with the likelihood of each, vary from patient to patient depending on their condition and anatomy. Accordingly, we discuss the benefits and risks of all available treatment options for vaginal symptoms with our patients, as recommended by the FDA, prior to starting any treatment.
3. We do not approach the use of MLTL treatment as a “one-size-fits-all” solution. Instead, we carefully evaluate each of our potential MLTL patients for candidacy PRIOR to any treatment. In fact, we decline to use the MLTL procedure in over 20% of our patients, including those who were referred to Academia specifically for the MLTL treatment.
4. We provide post-MLTL monitoring and treatment. To date, only one of our patients has experienced slight vaginal burning as a result of bacterial vaginosis (not related to the MLTL treatment), and which subsequently improved with antibiotics.
5. We use the MLTL to treat other conditions outside of the FDA’s specific area of concern, including success in treating Lichens Sclerosus with close vulvar surveillance with vulvar biopsy in most cases (with or without a vulvar biopsy, depending on the circumstances and if necessary to rule out more advanced pathology).

In summation, the FDA is largely concerned about the advertising of the MLTL and similar energy-based medical devices (mainly by the manufacturers of these devices) as effective treatments for certain conditions before it has fully tested, validated, and approved the advertised results. We do not advertise or use the MLTL for vaginal rejuvenation (as traditionally described), cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence, or sexual function. Instead, we approach the use of MLTL as just one option to consider and discuss with our patients for the treatment of many different conditions, including tremendously-resistant cases which were unsuccessfully treated with estrogen and clobetasol therapy.

Because the FDA's questions about the efficacy and safety (vaginal burning and scarification) of the MLTL are in sharp contrast to the positive results my patients have experienced with the procedure, I would like to conduct our own formal study as confirmation. To that end, it would help me tremendously if you would complete the following short survey and send it back at your convenience. Please do not hesitate to contact me if you have any further questions or concerns about the MLTL treatment at Academia.

Please understand that neither myself nor the practice has received, nor will receive, direct or indirect remuneration for conducting this survey. We will update you with the results of this survey as soon as all data is finalized. If you do not wish to receive this type of communication in the future, please simply check the "Opt Out" box at the bottom of the survey and return same.

To your continued health and happiness,

Assia Stepanian, M.D., F.A.C.O.G.

**ACADEMIA MONALISA SURVEY**

Patient Name: \_\_\_\_\_

Please confirm the following:

- |  |     |    |
|--|-----|----|
| 1. I had a pre-procedural MLTL evaluation with Dr. Stepanian.    | YES | NO |
| 2. Dr. Stepanian offered me the choice to use a vaginal estrogen | YES | NO |

If your primary concern was urinary incontinence, Dr. Stepanian told you that the MLTL should not be used for this problem alone because there is insufficient data to establish the success rate with urinary incontinence.

	YES	NO	N/A
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Dr. Stepanian did tell you that, in her experience, mild urinary incontinence may improve.

	YES	NO	N/A
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**HEALTH Questionnaire**

1. The date (month/year) of your first MLTL treatment: \_\_\_\_\_

2. What other symptoms or problems did you experience prior to MLTL procedure?  
\_\_\_\_\_  
\_\_\_\_\_

3. Have you seen improvement in these symptoms? Comments:	YES	NO
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4. After which treatment did you see improvement?    1            2            3

5. Did you experience symptoms of vaginal atrophy? I.e. dryness or pain associated with intercourse or speculum introduction?	YES	NO
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If Yes, which one?            Intercourse            Speculum Introduction for Exams

If Yes, did they improve with MLTL?	YES	NO
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6. Did you experience any of the following long-lasting/chronic effects after MLTL Treatment? (check all that apply)

- A) worsening of pain with intercourse
- B) vaginal burning
- C) vaginal scarring leading to pain with intercourse.

7. Have your results from MLTL treatment changed/improved the sexual experience in any way for your husband or partner?                      YES                      NO                      N/A

COMMENTS:

8. Would you recommend, or have you recommended MLTL to your friends based on your personal experience at Academia?                      YES                      NO

COMMENTS:

9. How happy are you with the success of your MLTL Treatment?

*Please circle. (1= Not at all happy, 5 =extremely happy)*

1      2      3      4      5

10. Please feel free to make any additional comments:

**CHECK THE BOX IF YOU WISH TO OPT OUT OF ALL SIMILAR COMMUNICATIONS:**

Thank you!

Assia Stepanian, M.D., F.A.C.O.G.