WOMEN'S HEALTHCARE OF PRINCETON
Progressive Gynecology Made Personal

MLT Information & Safety Review

Mona Lisa Touch (MLT) is a therapeutic procedure which uses light energy in the form of laser to treat gynecologic conditions including:

- diseases of the vulva such as Lichen Sclerosus
- symptoms of Genitourinary Syndrome of Menopause (GSM) such as
  - Vaginal dryness, painful intercourse
  - Urinary urgency, frequency, recurrent urinary tract infections (UTIs) and urinary incontinence

MLT is a carbon dioxide laser (CO2 laser) and is FDA cleared as a medical device. According to the FDA: "The DEKA SmartXide2 Laser System (Mona Lisa Touch) was cleared (K133895) for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery."
Currently, the application for Mona Lisa Touch is under review to the FDA for the specific indication of treatment for GSM. There are 44 scientific publications which indicate an 80-90 percent efficacy for significant improvement in symptoms of GSM and confirm the safety of the device when used according to manufacturer's guidelines. There are no reported serious adverse events related to the Mona Lisa Touch laser. A review of safety reports and claims in

1. The scientific literature through August 2019
2. The Manufacturer and User Facility Device Experience (MAUDE) database
3. The Bloomberg Law database through July 2019

yielded three publications detailing

- 46 presumptive laser—associated complications (none from Mona Lisa Touch)
- 30 patient-reported adverse events (MAUDE)
- NO claims of harm or injury (Bloomberg) from vaginal lasers used for treatment of GSM/VVA (vaginal atrophy)

There have been an estimated 200,000-500,000 vaginal/vulvar laser treatments performed in the US and over a million worldwide. As such, complications from laser treatments for GSM/VVA would be classified as "very rare" (less than 1 in 10,000) by the Council of International Organization of Medical Sciences (CIOMS) making this procedure overall extremely safe.