

MonaLisa Touch[®]

Indications/ FDA Clearance

The MonaLisa Touch Laser is indicated 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 thoracic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery.

Contraindications

Therapy using the MonaLisa Touch laser is contraindicated for those patients who:

- Have vaginal, cervical, or other lesions in the treatment area that have not been evaluated and diagnosed
- Have active vaginal or vulvar infection i.e., (herpes, candida, STDs)
- Pregnant or within 3 months postpartum
- Have prolapse beyond hymen
- Have history of radiation to vaginal/ colo-rectal tissue
- Have history of reconstructive pelvic surgery with "mesh kits"
- Have a history of impaired wound healing
- Have a history of keloid formation
- Known anticoagulation treatment or thromboembolic condition

NOTE: History of Tension Free Vaginal Taping (TVT) type sling for incontinence is NOT a contraindication.

NOTE: A qualified practitioner is solely responsible for evaluating each subject's suitability to undergo laser treatment and for informing those being treated about any risks involved with the treatment, pre-and postoperative care, and any other relevant information.