



Clinical Guide - Zmed-Laser for Hysteroscopy

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A.1. Hysteroscopy

A.1.1. Introduction

Myomas, commonly known as uterine fibroids, are noncancerous growths of the uterus that affect about 30% of all women during their childbearing years.

Zmed-Laser minimally invasive laser hysteroscopy offers women of childbearing age with a safe and effective method to remove uterine myomas and vulva lesions. The advanced laser technology assures fast recovery and minimal discomfort for the woman treated. Also, the laser treatment helps to avoid (hysterectomies) scars on the myometrium that are frequent in other endo-uterine surgical techniques by conserving the endometrial tissue

Advantages of the Zmed-Laser hysteroscopy procedure include:

- Minimally invasive – can be performed in the clinic.
- Almost no complications.
- Reduced time required and costs for OR.
- Saline environment.
- Specially designed fibers with tactile feedback.

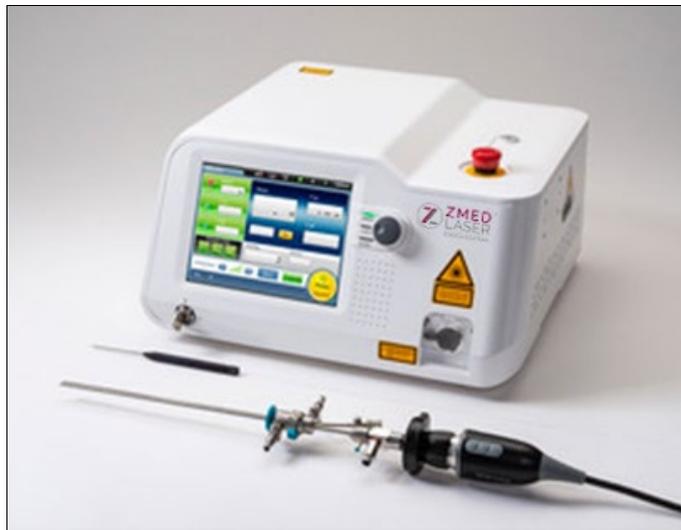


Figure 1. ZL1000 Laser Kit

A.1.2. Training Requirements

The ZL1000 system is designed to be operated only by personnel properly trained in its handling and use. All personnel who operate the system must read the operator's manual. This includes physicians, nurses, technical staff, and other professional staff members.

The physician is responsible for contacting the local licensing agencies to determine any credentials required by law for clinical use and operation of the device.



Warning

The ZL1000 system, the Zmed-Laser hysteroscopy fiber and the Zmed-Laser hysteroscopy procedure may only be used and practiced on patients by a licensed and properly trained physician.

A.1.3. Intended Use and Indications

- Myomas
- Polyps
- Septum
- Adhesion/Asherman syndrome
- Dysmorphic uterus
- Isthmocele
- T-Shape Uterus

A.1.4. Contraindications

- Pregnancy (currently or recently pregnancy).
- History of keloid formation.
- Therapy with oral anticoagulant.

A.1.5. Adverse Effects of the Treatment

The following adverse effects may occur when using the Zmed-Laser ZL1000 laser system and the Zmed-Laser treatment:

- Bleeding
- Infection
- Hematoma
- Skin necrosis
- Pain

A.1.6. Realistic Expectations

The degree of response to the Zmed-Laser for hysteroscopy treatment differs from one patient to another and depends on the clinical and physiological conditions prior to performing the procedure. Some patients may experience better responses than others. The surgeon's experience also contributes to the success of the treatment.

A.1.7. Pre-Treatment Preparations**A.1.7.1. Pre-Operative Evaluation**

- All patients should be screened during an initial office visit, consisting of a complete medical history and examination to assess their general condition, history, and lifestyle.
- A thorough medical history should be obtained at the consultation. For patients with pre-existing cardiovascular or respiratory conditions, it may be prudent to request medical clearance by their primary care physicians, cardiologist, or pulmonologist. The physician should be particularly aware of those patients with impaired liver function, hepatitis C, chronic active hepatitis B, and alcoholic liver disease.
- A surgical history should be obtained. Physical examination is an essential part of the consultation. The patient should be in a gown and examined in the standing position.
- After verbal discussion and written presentation of the risks and benefits of the procedure, informed consent should be obtained.
- Other specific diagnoses may include:
 - Rectal examination
 - Anoscopy/proctoscopy
 - Anal endosonography
 - MRI scan

A.1.7.2. Recommended Preoperative Screening Tests

- Complete blood count.
- Comprehensive metabolic panel.
- Coagulation studies – PT/PTT/INR and others if history of bleeding during procedures exists.
- ECG for patients aged 35 and older.
- Chest RX AP plus lateral for patients aged 60 and older or if patient has a history of heart disease.

A.1.8. Pre-Surgery Preparation**A.1.8.1. Pre-Surgery Site preparation (Seton)**

The fistula tract should be prepared with a seton for at least 12 weeks, as indicated by the physician. The use of the seton leaves a passage open to drain the pus that has formed in the abscess cavity over time. After opening the abscess this seton is placed in and left for over 12 weeks, according to the practitioner and the status of the patient.

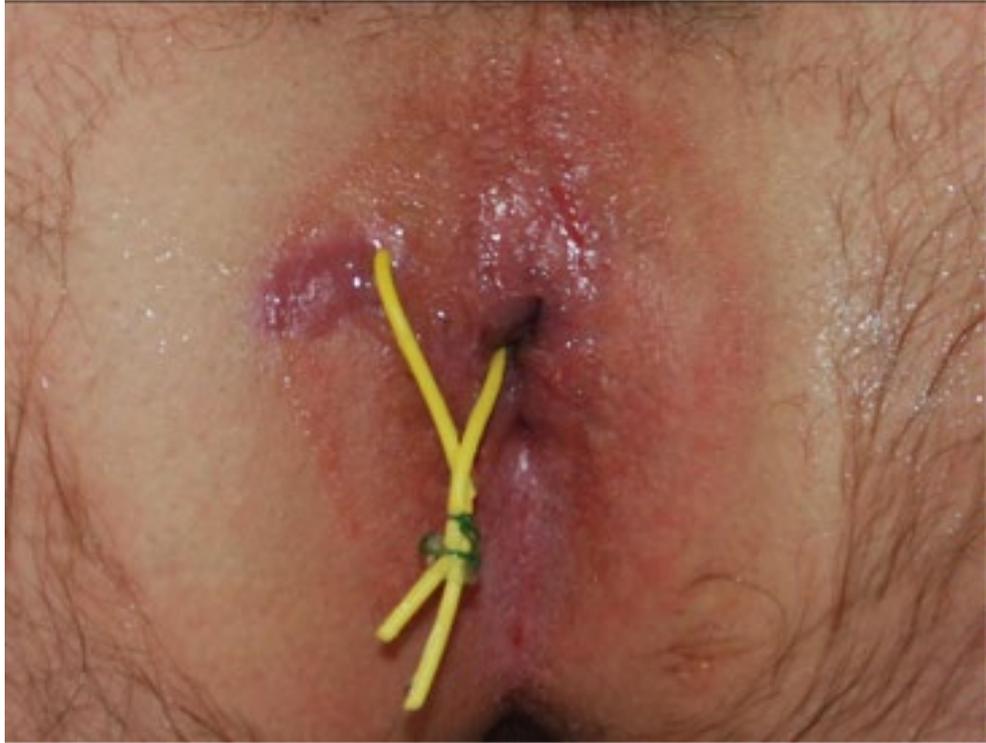


Figure 2. Seton

A.1.9. Performing the Procedure

A.1.9.1. Required Equipment

The required equipment for this procedure includes the following:

- ZL1000 1470nm diode laser
- Radial emission fiber
- Conical fiber
- Hysteroscope with a 5Fr. (1.67mm) working channel

A.1.9.2. Anesthesia

Epidural or general anesthesia should be administered according to the physician's discretion. In some simple cases, patients may prefer sedation and local anesthesia.

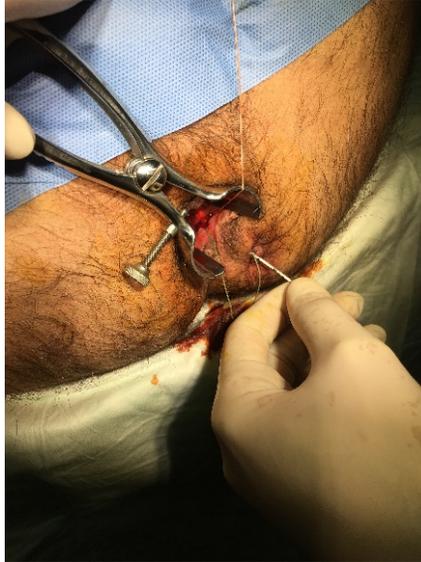
A.1.9.3. Laser Procedure

Figure 3. Introducing the Laser Fiber into the Fistula

To perform the procedure:

1. With patients in the lithotomy position, identify the external and internal anal openings of the fistula tract (injection of methylene blue dye/hydrogen peroxide may be used).
2. Before removing the seton, attach a rubber loop and pull into the tract. Attach the fiber tip to the rubber loop and pull the fiber into the fistula tract.

***Warning***

Make sure that all people in the treatment room wear appropriate safety goggles.

3. Prepare the laser for treatment:
 - Set the laser to continuous wave (CW) mode.
 - Set the desired power (from 10W to 14W, as per the physician's decision).

4. With the tip of the fiber positioned at the internal opening, deliver the laser energy (in CW mode), while slowly pulling the fiber through the fistula tract

Laser radiation causes shrinkage of the surrounding tissue, allowing primary closure of the fistula tract.

A.1.10. Medications

Pre-operative medications vary, based on the clinician's discretion and patient's requirements. Some clinicians may provide an anxiolytic, such as Lorazepam or Midazolam, before the procedure. Clonidine, an α -2 adrenergic receptor anti-hypertensive medication, may be employed due to increasing the threshold for possible lidocaine toxic effects. Intramuscular narcotics, such as Meperidine, may

be employed to dampen the discomfort associated with the infusion of tumescent anesthesia. Finally, an antihistamine such as Hydroxyzine is often employed for additional sedation and to offset any nausea produced by the medications mentioned herein.

After the procedure, an oral antibiotic should be prescribed for five days or more (Ciprofloxacin: 200 mg - Metronidazole: 1 g).

Intraoperative IV antibiotic should be administered according to the physician preference.

A.1.11. Post-Treatment Care

- The patient should return for a follow up visit one week after the procedure for evaluation of the treated site.
- The patient should be informed to wait for a minimum of eight days before resuming normal activities, particularly sporting activities where mechanical shocks may be experienced.