Clinical Article Summary

# Initial experience with the graphical user interface for laser parameters setting of a new thulium fibre laser source device for urinary pathologies treatment

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## Abstract

**Background and objective:** We aimed to evaluate the concordance between the pre-settings ranges of thulium fibre laser (TFL) (Coloplast TFL Drive, Denmark) with easy-to-use graphical user interface and the laser settings used by a high-volume endourologist during surgical procedures.

**Materials and methods:** In October 2022, we prospectively collected data of 67 patients who underwent TFL Drive (Coloplast, Denmark) for the management of urinary stones. Urothelial tumour (upper tract urinary cancer (UTUC) and bladder) 200 and 150 µm laser fibers were used for procedures. Stones characteristics (size and density) tumours and stenosis localizations, laser-on time (LOT), and laser settings were recorded. We also assessed the ablation speed ($mm^3/s$), laser power (W), and Joules/$mm^3$ values for each lithotripsy.

**Results:** A total of 67 patients took part in the study. Median age was 52 (15–81) years. 55 (82%), 8 (12%), and 4 (6%) patients presented urinary stones, urothelial tumour, and stenosis, respectively. Median stone volume was 438 (36–6027) $mm^3$ and median density was 988 (376–2000) HU. Median pulse energy was 0.6 (0.3–1.2), 0.8 (0.5–1) and 1 J for urinary stones, urothelial tumour and stenosis respectably. Endoscopically stone-free rate was 89%. Graphical user interface and surgeon accordance with the safety range were observed in 93.2%, 100% and 100% for urinary stones, UTUC and stenosis, respectively.

**Conclusion:** During endoscopic procedures for urinary stones treatment, it is frequently needed to change laser parameters. These new TFL and GUI technology parameters remained in the pre-set security range in 94.1% of procedures.

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### Coloplast Key Takeaways

- The first published clinical results with the Coloplast TFL Drive.
- No consensus amongst medical professionals on the most effective clinical parameters for laser lithotripsy.
- This study suggests that lower frequency and total power levels may offer a safer and more efficient approach.
- Optimal settings may require adjustments based on stone composition, HU, technique, distance between stone and laser tip, equipment, fiber size and type of ureteroscope.
- Study results suggest that laser lithotripsy using the recommended settings outlined in the TFL Drive GUI can achieve effective stone fragmentation.
- The surgeon remains in accordance with the pre-settings range of the Coloplast TFL Drive in 94.1% of procedures.

**Coloplast TFL Drive**
**BRIEF STATEMENT**

**Indications**

The Coloplast TFL Drive laser device and its accessories are intended for incision, excision, resection, ablation, coagulation, hemostasis, and vaporization of soft tissue with or without an endoscope, in the following indications: Urology, Lithotripsy, Gastroenterological Surgery and Gynecological Surgery.

**Contraindications**

The use of the laser is contraindicated:

- In patients whose general medical condition contraindicates surgical intervention.
- When appropriate anesthesia is contraindicated by patient history or inability to receive anesthesia.
- Where tissue (especially tumors) is calcified.
- For hemostasis of vessels with diameters over approximately two millimeters.
- Where laser therapy is not considered the treatment of choice.
- In patients who have recently undergone radiotherapy. Such patients may be at greater risk of tissue perforation or erosion.
- In patients unable to receive endoscopic treatment.
- In patient suffering from bleeding disorders and coagulopathy.
- Diagnosed with acute or chronic prostatitis, prostate cancer, or severe urethral stricture.
- Diagnosed at the time of treatment with acute or chronic urinary tract infection.

**Other considerations requiring Physician's clinical judgement:**

- Patients with compromised renal function or upper urinary tract obstructive diseases.
- Patients who still wish to have children.
- Patients with an ASA classification of physical status 5.
- Patients with a prostate gland > 120g.

**Warnings and Precautions**

Clinical studies have shown that patients who have undergone radiation therapy present a greater risk of perforation or tissue erosion. The Coloplast Drive Laser System is a surgical device that should be used only by physicians or surgeons who have been thoroughly trained in laser surgery. Surgeons using Coloplast TFL Drive Laser System must understand the laser's unique properties prior to using the device.

As with conventional endoscopic surgery, the possibility of complications and adverse events (such as chills, fever, edema, hemorrhage, inflammation, tissue necrosis or infection) may occur following treatment. In extreme cases, death may occur due to procedural complications or concurrent illness. The laser may not be effective for coagulation in massive hemorrhage situations. The surgeon must be prepared to control hemorrhages with alternative non-laser techniques, such as ligature or cautery. The risk of infection and scarring associated with any surgical procedure has to be taken into account. Tissue perforation may result if excessive laser energy is applied. This could occur through the use of excessive laser power or the application of a correct power for excessive periods, particularly in diseased tissue. The use of mechanical pressure on the Single-Use and Reusable Optical Fiber devices does not increase its cutting or vaporization effects but may induce bleeding, thermal damage and fiber destruction.

The manufacturer has no clinical information or experience concerning the use of the Laser System on pregnant women or nursing mothers. There is no guarantee that treatment with the Laser System will entirely eliminate the disease. Repeated treatment or alternative therapies may subsequently be required.

**Potential Complications**

Complications and risks are the same of the conventional laser surgery. Acute pain may occur immediately following laser therapy and may persist for as long as 48 hours. Immediately following laser therapy, the patient may experience fever and leucocytosis, which are commonly associated with tissue destruction. These generally resolve without treatment. Laser ablated tissue may become necrotic or infected after treatment. In case of concerns about any possible infection, appropriate treatment should be carried out.

Acute complications and non-thermal risks include induced hemorrhage, ulceration, perforation, edema, pain, fever, leukocytosis, and chills. Critical complications and thermal risks include healing delay, perforation, stenosis, delayed hemorrhage, sepsis, and embolism.

The following complications could be serious and could result in death:

- Patients may experience bleeding at the site of laser therapy. Haematocrit analysis after treatment is recommended to identify this potential complication.
- Sepsis can result from performing any surgical procedure. In case of concerns about any possible sepsis, appropriate evaluations should be made.
- Perforation may occur as a result of laser treatment. In order to diagnose perforations, patients must be carefully followed post-operatively with appropriate tests.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

**Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN

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**Coloplast TFL Drive Laser Fibers BRIEF STATEMENT**

**Indications – Single Use Lateral and 150µm Optical Fibers**

Single Use Lateral and 150µm Optical Fibers are intended to be used to deliver the laser radiation to the target tissue when used with any cleared/certified surgical laser with operational wavelengths between 532 nm – 2200 nm equipped with SMA 905 or SMA 906 or compatible connector, as per the indications of the laser device used with.

**Indications – Single Use and Reusable Optical Fibers**

Single Use and Reusable Optical Fibers are intended to be used in conjunction with any cleared surgical laser distributed by Coloplast equipped with SMA 905 or SMA 906 or compatible connector for use in general surgical applications (incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in contact or non-contact mode). Optical Fibers are also indicated for use in open or closed endoscopic applications where incision, excision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors or lesions, tissue vaporization, hemostasis and or coagulation may be indicated.

The Optical Fibers are indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, vascular surgery, neurosurgery, plastic surgery, ENT/otolaryngology, endovenous occlusion of the greater saphenous vein in the patient with superficial vein reflux and laser assisted lipolysis. Optical Fibers are also intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue, and for use in lithotripsy.

Optical Fibers are indicated for use with laser devices emitting radiation from 532 nm to 2100 nm, with pulsed and continuous wave (CW) emission mode, and, but not limited, for use with Diode laser, Argon, KTP/532, Ho:YAG, Nd:YAG, Tm:YAG pulsed and continuous wave CW laser devices.

Optical Fibers may be used in surgical specialties or procedures for which compatible lasers have received regulatory clearance: for a complete information about applications, contraindications, precautions and warnings when using Optical Fibers it is necessary to refer to the applicable laser device User Manual.

**Warnings and Precautions - Single Use, Single Use 150µm and Reusable Optical Fibers**

Optical Fibers shall be used by trained and qualified users only. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to a device failure which, in turn, may result in patient injury, illness or death (For Single Use Fibers Only). On patients with confirmed or suspected Transmissible spongiform encephalopathies (TSEs), also known as prion disease, use only Single-use Sterile Optical fibers.

**Potential Complications - Single Use, Single Use 150µm and Reusable Optical Fibers**

Complications that could occur during laser treatments include local and/or systemic infection, thermal changes to the surrounding structures, local hematoma, dissection and perforation, tissue adhesion, distal tip detachment, and discomfort during and/or after (laser) energy application. In the unlikely event of a detached tip, it may be visually located through an appropriate scope and removed using forceps. Irrigate the area thoroughly to remove any traces of the tip.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

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