Optima

Think Outside the Eye

Stellar Optima

Treatment Hand-Piece

User Manual

Lumenis®

Energy to Healthcare

Caution

US federal law restricts this device to sale by or on the order of a physician.

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Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE)

In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE), any item which is marked with the crossed-out wheelie bin symbol must not be disposed of as unsorted municipal waste, but segregated from other waste types for eventual treatment and recovery at an approved recycling facility.

By returning waste electrical and electronic equipment via the correct segregated disposal channel, users can ensure the environmentally sound treatment and disposal of the waste equipment, thereby reducing the potential for any environmental or health risks that could arise as a result of incorrect disposal.

Lumenis provides web-based collection, recycling and reporting arrangements to the business end-user for equipment marked with the crossed-out wheelie bin.

Visit http://www.lumenis.com/Service-Support/Recycle to understand what arrangements Lumenis has made in each EU Member State.

Federal Communications Commission (FCC) Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules. Operation is subject to two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Lumenis Ltd.) could void the user's authority to operate the equipment.

Industry Canada Requirements

This device complies with Innovation, Science and Economic Development Canada's license - exempt RSS standard(s). Operation is subject to two conditions:
(1) This device may not cause interference,
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

(1) l'appareil ne doit pas produire de brouillage,

(2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

- This Class B digital apparatus complies with Canadian ICES-003.
- Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada.

Radiation Exposure Statement:

This equipment complies with FCC and IC RF radiation exposure limits set forth for an uncontrolled environment.

Use of this Manual:

The Stellar Optima Treatment Hand-Piece accessory is designed to meet international safety and performance standards. Personnel operating the system must have a thorough understanding of the proper operation of the system.

This manual has been prepared to aid medical and technical personnel to understand and operate the system. Do not operate the system before reading this manual and gaining a clear understanding of the operation of the system. If any part of this manual is not clear, contact your Lumenis representative for clarification.

The information provided in this manual is not intended to replace physician training or professional training on the clinical use of the Stellar Optima treatment Hand-Piece. Such training should include a review of published literature, seminars, workshops and appropriate preceptorships. Contact your Lumenis representative for current information on available training.

This manual should always accompany the accessory, and its location must be known to all personnel operating the system. Additional copies of this manual are available from your Lumenis distributor.

System and accessory specifications subject to change without notice.

For further information about Lumenis, visit the Lumenis Website: http://www.Lumenis.com or send email to information@Lumenis.com.

Device Description:

The Device is supplied in a suitcase. It consists of an IPL connector (Optima Lightguide adaptor), fiber, and plastic handle and trigger button via BLE battery operated, and disposable tip. The fiber transmits the IPL energy from the IPL source system to the treatment area through the fiber tip. The communication between the device and the IPL system is done via BLE module, operated using trigger button.

The Treatment hand-piece accessory includes Lightguide Identification mechanism, enabling the IPL system to recognize if the accessory is connected.

Intended Use:

The Stellar Optima Treatment Hand-piece, with the Intense Pulsed Light (IPL) hand-piece (with a spectrum of 400-1200 nm) is intended for aesthetic and dermatological skin procedure applications, and indicated for:

Benign cutaneous vascular lesions, including facial, truncal and leg telangiectasia, and erythema of rosacea.

Intended User:

Patient treatment is the responsibility of licensed practitioners

PreOperative Instructions:

The following technique is required to ensure safe use of the Stellar Optima Treatment Hand-Piece:

- Do not bend the fiber more than 30mm radius.
- Extract the treatment hand-piece from its original suitcase and place it on a dedicated cradle.
- Clean the Lightguide adaptor optical surface and the fiber edge using 70% alcohol wipes before each use.
- Make sure to attach disposable tip to fiber end to protect the fiber and treated area before operating the Treatment hand-piece.
- Avoid dropping, stepping over, stretching and pulling the fiber cable to prevent damage.

Operating Instructions:

- Pull the Battery Contact Insulator to enable battery operation if attached.
- The green LED should be indicating the hand-piece is ON.
- Connect the Lightguide adaptor to the IPL source.
- Use the trigger button to prompt IPL energy delivery through the fiber to the treatment area.
- The BLE is used to deliver the trigger request, to transfer data such as hand-piece SN, number of pulses etc.

PostOperative Instructions

- Dispose of the single use tip
- Place the Treatment Hand-Piece back to its dedicated cradle or store it back into its original suitcase after covering the Lightguide adaptor with its original cap cover.

Protective eyewear:

Protective eyewear is provided with Lumenis IPL systems, and must be used when treating with the Optima Treatment Hand-piece.

Coupling Gel:

Using refrigerated (6 – 10°C) coupling gel on the skin serves to control discomfort and provide a light-coupling medium between the fiber tip and the skin surface. The coupling gel is provided with Lumenis IPL system.

The gel may be purchased in 0.25 liter and 1.0 liter bottles.

Disposable kit:

The Stellar Optima Treatment hand-piece should be used only when a disposable tip is connected, and with corneal shields placed on the patient eyes. A disposable kit is provided as a starter kit inside the accessory suitcase, and can be purchased separately.

Device images:

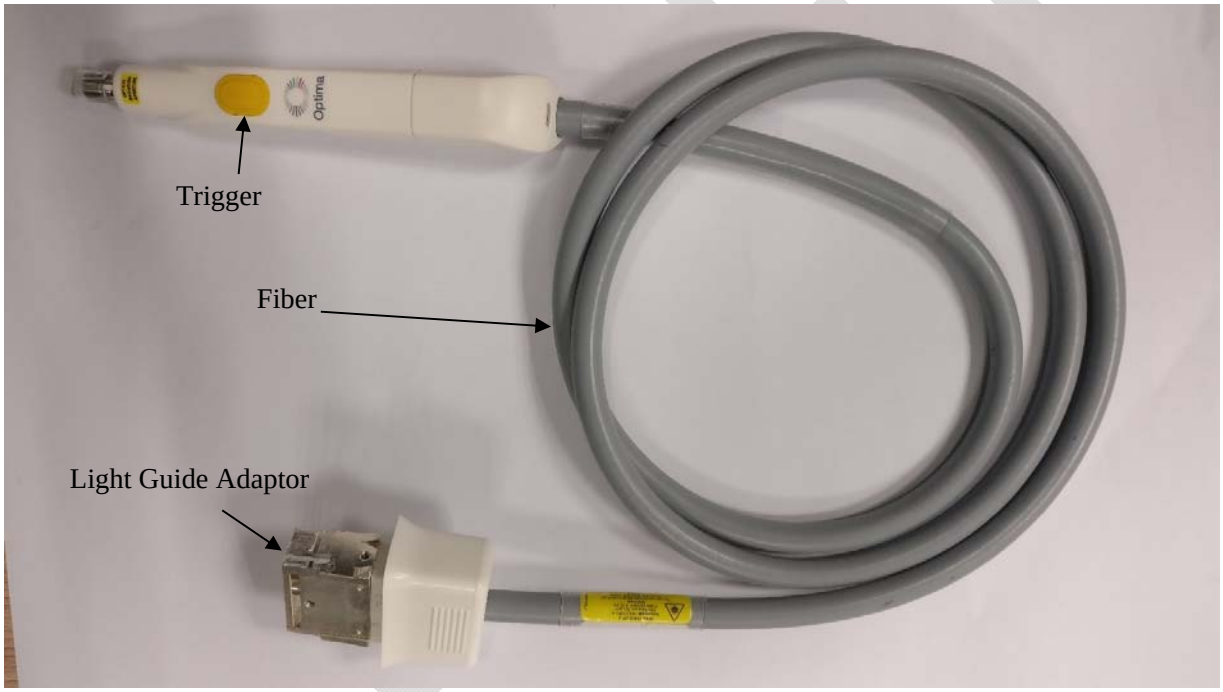

Figure 1: Stellar Optima Treatment hand-piece

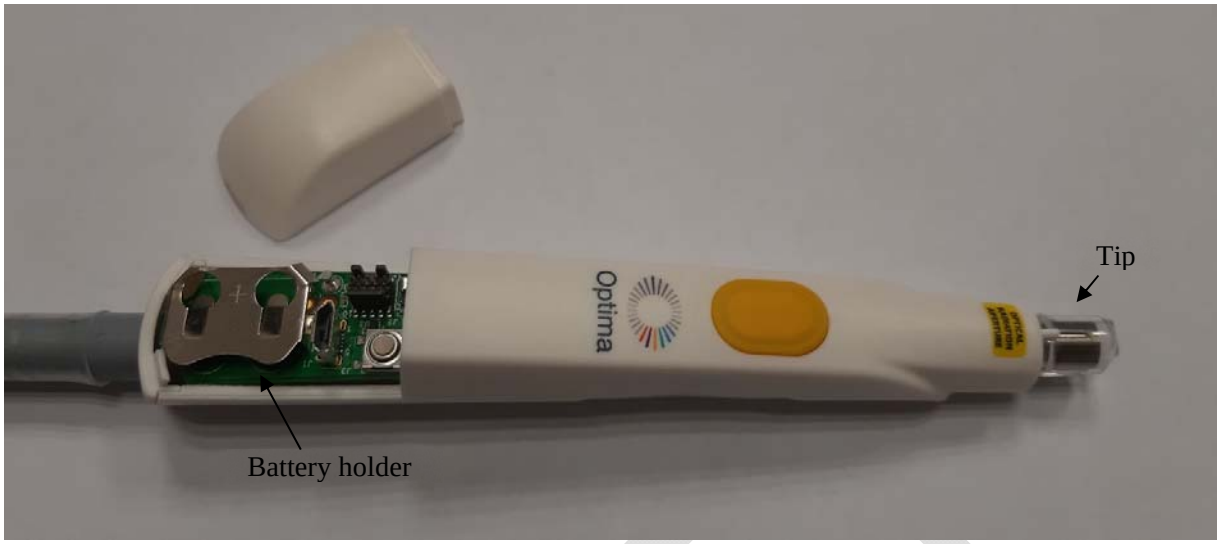

Figure 2: Stellar Optima Treatment hand-piece without battery cover.