



ONETRAC™ LX

Single-Use Cordless Retractor with Integrated Multi-LED Light Source

Instructions for Use

MD

CE UK
CA
Rx Only 2797 0086

REF C100210 C100220 C100230 C100240 C100250
C100260 C100270 C100280 C100290

DEVICE DESCRIPTION

ONETRAC LX is a single-use cordless retractor with integrated multi-LED light source. ONETRAC LX is available in several blade sizes. It is a single-use device provided sterile and is not intentionally manufactured using natural rubber.

PERFORMANCE CHARACTERISTICS

ONETRAC LX is a handheld instrument that provides soft tissue retraction during surgery (essential performance), provides illumination to the surgical site when integrated lighting feature is turned on and provides smoke evacuation from the surgical field when attached to a vacuum source. Once the device is illuminated the device provides a minimum of 180 minutes of continuous illumination. The device is intended to be used in a surgical suite/operating room with a maximum operating temperature (local ambient temperature) up to 25 deg C.

CLINICAL BENEFIT

The indirect clinical benefit intended is enhanced visibility in the surgical site.

INTENDED USE/PURPOSE AND INDICATIONS FOR USE

The single-use lighted retractor is intended to retract soft tissue, provide illumination and enable smoke evacuation in the surgical site.

The single-use lighted retractor is indicated for providing visibility through the retraction of soft tissue, illumination of the surgical cavity, and smoke evacuation when attached to hospital suction source.

INTENDED USER

The device is intended for use by qualified medical personnel possessing training in the surgical procedure being performed.

INSTRUCTIONS PRIOR TO USE

1. Verify that the EtO indicator sticker on the unit box is BLUE - do not use if EtO indicator sticker on unit box is RED.
2. Inspect sterile barrier for damage - if the sterile barrier packaging is damaged do not use and source a new device.
3. Confirm activator tab (A, F) is only partially inserted into the handle while device is sealed in the sterile barrier - if activator tab is depressed into the handle within the sealed sterile packaging do not use and source a new device.
4. Inspect each device for damage - if device is damaged do not use and source a new device.
5. Confirm expiry date prior to use - if current date is beyond the expiry date, do not use and source a new device.
6. Confirm device functionality according to instructions for use - if device is defective, do not use and source a new device.



WARNINGS

- If EtO indicator sticker is RED or if the sterile barrier packaging is damaged, contents may not be sterile. Do not resterilize.
- If used beyond expiry date, contents may no longer be sterile and may not meet essential performance. Do not resterilize.
- Use of a damaged device may result in patient or user injury.

INSTRUCTIONS FOR USE

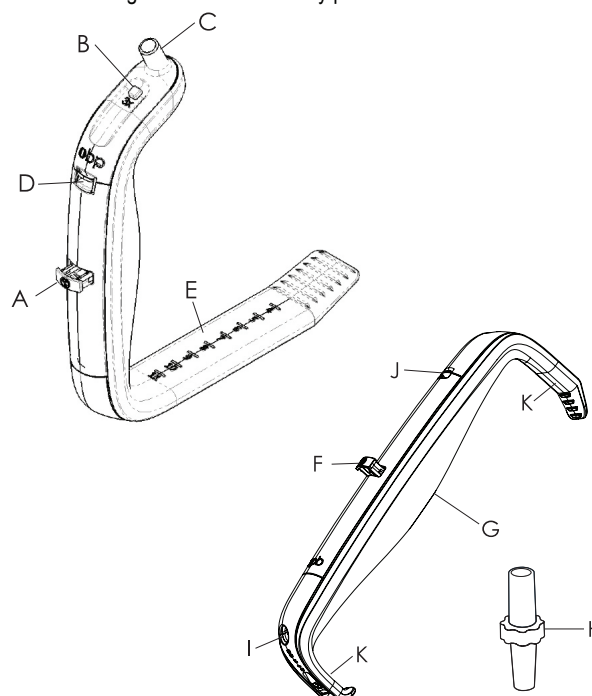
SINGLE-BLADE RETRACTOR INSTRUCTIONS

1. **Battery Activation:** Depress colored battery activator tab (A) into handle, do not remove from handle.
2. **Lighting:** Before using the device, confirm all LEDs on the blade turn on by pressing the black on/off button (B) to cycle through each different LED lighting configuration. Once all LEDs are on, press button (B) a final time to turn off all lights. If illumination is intermittent, retrieve a new device. When device illumination slowly turns off and on autonomously, the batteries are fully depleted. Turn off light when not in use to preserve battery life.

3. **Smoke Evacuation:** If smoke evacuation is desired, attach smoke evacuation tubing (not included) by press-fitting the female tubing connector onto the smoke evacuation port (C) on the handle. Confirm the tubing is securely attached to the smoke evacuation port (C).
4. **Battery Disposal After Use:** Prior to disposal of device, with battery door facing downward, open the battery door by pulling on the latch (D). The batteries will fall into the battery door enabling touch-free disposal. Dispose of lithium primary batteries according to state and local regulations and/or facility procedures.
5. **Device Disposal After Use:** Once batteries are removed, treat used device as biohazardous infectious material and dispose of in accordance with state and local regulations and/or facility procedures.

DUAL-BLADE RETRACTOR INSTRUCTIONS

1. **Battery Activation:** Depress colored battery activator tab (F) into handle, do not remove from handle.
2. **Lighting:** Before using the device, confirm all LEDs on both blades turn on: Press the black rocker button (G) 2x closest to the blade you are activating. Each press of rocker button (G) will cycle through a different LED lighting configuration. Press rocker button (G) a 3rd time to turn off lights. Repeat on opposing blade. If illumination is intermittent, retrieve a new device.
3. **Smoke Evacuation:** If smoke evacuation is desired, insert narrower side of included smoke evacuation tubing adapter into the handle port (I) on the opposing side to the blade being used. Attach smoke evacuation tubing (not included) by press-fitting the female tubing connector onto the smoke evacuation tubing adapter (H). Confirm the tubing is securely attached to the smoke evacuation port. Twist smoke evacuation tubing adapter to release and repeat on opposing port to enable smoke evacuation on opposing blade.
4. **Battery Disposal After Use:** Prior to disposal of device, with battery door facing downward, open the battery door by pulling on the latch (J). The batteries will fall into the battery door enabling touch-free disposal. Dispose of lithium primary batteries according to state and local regulations and/or facility procedures.
5. **Device Disposal After Use:** Once batteries are removed, treat used device as biohazardous infectious material and dispose of in accordance with state and local regulations and/or facility procedures.



⚠️ WARNINGS

- Use of alternative smoke evacuation tubing adapters may result in loss or reduced suction and therefore reduced visibility in the surgical cavity during cautery and exposure to fumes from surgical smoke.* Only applicable to ONETRAC LX.
- Exercise caution while dissecting around the device. Direct contact with an electrosurgical instrument may cause physical damage to the device or the patient.
- Applying excessive force to tissue with APPLIED PART (E, K) may result in tissue damage and/or device breakage. In case of device breakage during use, ensure no fragments or batteries remain in patient and retrieve a new device.
- Unauthorized modification of the device (for example-reprocessing, replacing battery or re-sterilizing) may cause damage to the battery resulting in chemical burns or fire/explosion and may result in a non-sterile device.
- Improper disposal of used device may lead to spread of infection.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ONETRAC LX. Otherwise, degradation of the performance of the ONETRAC LX could result.
- Do not remove sterile device tray from protective unit box until use. Preemptive removal may result in damage to sterile barrier which may cause patient infection.

⚠️ CAUTION

- Do not submerge device in fluid, as this may result in loss of light function.
- In case of loss of illumination during use, retrieve alternative light source.
- Possibly hazardous optical radiation emitted from the LEDs. Do not stare at the LEDs while on as this may be harmful to the eye.
- In extreme cases, electromagnetic disturbances may cause the light to turn OFF. To turn the light back ON, press the ON/OFF button.
- Surgical smoke may pose a health hazard. In case of loss of smoke evacuation during use, detach smoke evacuation tubing from device and use tubing directly.
- The surface temperature of the distal LEDs (yellow) and the directly surrounding blade cover (blue) may reach temperatures of 41-52°C when idle at an operating environment of 20°C. If these surfaces directly contact the patient, unintended, localized thermal injury to tissue may occur. The use of the smoke evacuation feature will reduce surface temperatures.

DEVICE DISPOSAL

After the procedure, this device may be contaminated with potentially infectious substances of human origin and should be disposed of in accordance with institutional guidelines.

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

REPORTING OF SERIOUS INCIDENTS

PLEASE NOTE: If a serious incident is suspected from using the ONETRAC LX device, report the details of the incident to CooperSurgical via the online complaint form <https://www.coopersurgical.com/contact-us/customer-complaint-form-med-dev/>, by email at ProductSurveillance@coopersurgical.com, or by phone number +1 203-601-5200 Ext. 3100 and to the local Health Authority in your country. A serious incident may have caused or contributed to a death, a delay in a procedure which resulted in death or serious injury, or a malfunction that could have caused an adverse event.

Conforms to IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+A1:2020, INTERNALLY POWERED ME EQUIPMENT; CISPR 11 CLASS A, GROUP 1

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WARRANTY

Please visit www.coopersurgical.com "Terms and Conditions" page for warranty information. CooperSurgical®, Inc. should be notified immediately via phone or email of any defective units.

Glossary of Symbols

Source: ISO 15223-1, ISO 7000 and IEC 60601-1

Symbol	Title
	Packaging unit
	Catalogue number
	Model number
	Batch code
	Country of manufacture ("CC" shall be replaced by either the two letter or three letter country code)
	Date of manufacture
	Use-by date
	Sterilized using ethylene oxide
	Single sterile barrier system
	Single sterile barrier system with protective packaging outside
	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Medical Device
	Product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use
	Keep dry
	Fragile, handle with care
	Authorized representative ("XX" shall be replaced by either the two letter or three letter country code)
	Importer
	Manufacturer
	The product conforms to the UK Device Medical Regulation 2002, as amended. The product can be freely marketed in Great Britain (England, Wales and Scotland)
	Contains two (2) non-rechargeable Li-metal batteries. In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally - do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waste. Contact local WEEE disposal sites.
	Type BF applied part
	Vertically falling drops; no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical
	Caution



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