



ONETRAC™ LXS Yankauer

Single-Use Yankauer Suction Device with Integrated Cordless Radial LED Light Source

Instructions for Use

MD

 CE UK
CA

Rx Only 2797 0086

REF C110200 C110210 C110220

DEVICE DESCRIPTION

ONETRAC LXS Yankauer is a single-use suction device with integrated cordless radial LED light source. The ONETRAC LXS Yankauer is available in multiple configurations and is provided with a stylet. It is a single-use device provided sterile and is not intentionally manufactured using natural rubber latex.

PERFORMANCE CHARACTERISTICS

ONETRAC LXS Yankauer is a handheld instrument that provides aspiration from the surgical field (essential performance) when attached to a vacuum source and provides illumination to the surgical site when the integrated lighting feature is turned on. 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 suction tool is intended to aspirate and provide illumination in the surgical site.

The single-use lighted rigid suction cannula is indicated for enhancing visibility to a sub-cutaneous surgical field through aspiration and illumination of the surgical cavity.

INTENDED USER

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

INSTRUCTIONS PRIOR TO USE

1. Inspect sterile barrier for damage – if the sterile barrier packaging is damaged do not use and source a new device.
2. Confirm activator tab (A) 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.
3. Confirm stylet is packaged inside the sterile barrier with the device - if stylet is not packaged with the device, 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.



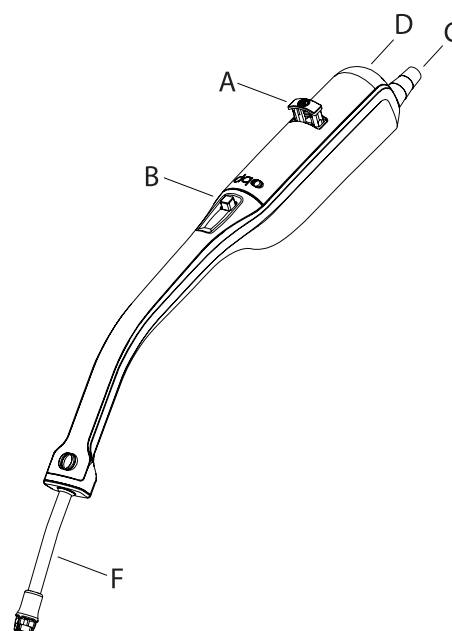
WARNINGS

- 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

1. **Battery Activation:** Depress colored activator tab (A) into handle, do not remove from handle.
2. **Lighting:** Before using the device, confirm LED turns on by pressing the black on/off button (B). If illumination is intermittent or does not turn on, 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. **Suction:** Attach suction tubing (not included) by press-fitting the female tubing connector onto the suction port (C) on the handle. Confirm the tubing is securely attached to the port (C), and confirm vacuum power at distal suction tip before use. Use included stylet to unclog rigid suction cannula if necessary. **WARNING:** If device cannot be unclogged, source a new device.
4. **Battery Disposal after use:** Prior to disposal of device, with battery door facing downward, open the battery door by pressing on the latch (D) and by lifting the battery door away from the handle. Continue to lift the battery door until the batteries are sitting within the battery door. Tilt the battery door until the batteries fall out of the battery door and into the battery disposal container. Dispose of lithium primary batteries according to state and local regulations and/or facility procedures.



WARNINGS

- Exercise caution while dissecting or cauterizing 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 (F) 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 LXS. Otherwise, degradation of the performance of the ONETRAC LXS 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.

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 LXS Yankauer 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

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)
	Type BF applied part
	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.
	Vertically falling drops; no harmful effects when the enclosure is tilted at any angle up to 15° on either side of the vertical
	Caution

© 2025 CooperSurgical Inc.

CooperSurgical®

Phone: (800) 243-2974

Fax: (800) 262-0105

International:

Phone: +1 (203) 601-9818

Fax: +1 (203) 601-4747

www.coopersurgical.com



CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

UK Responsible Person
Research Instruments Ltd
Bickland Industrial Park,
Falmouth, Cornwall TR11 4TA, UK



CooperSurgical Distribution B.V.
De Grinderij 1, 6049 GH, Herten
The Netherlands



Origio GmbH
Frankfurt am Main/DE
c/o Ernst & Young AG
Maagplatz 1
8005 Zürich
Switzerland