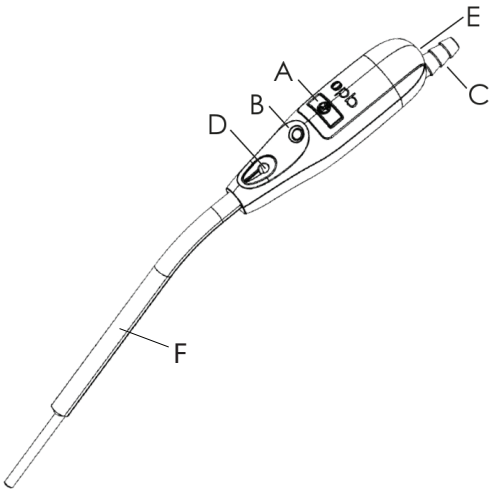
simple, bright ideas.

ONETRAC® LXS Frazier

REF C110310, C110320



English

Contains one (1) non-rechargeable Li-metal battery. Dispose of battery in accordance with local hazardous waste regulations/requirements.

Do not reuse, single use device

REF Catalog number

LOT Lot number

Use by date

Date of manufacture and country of manufacture

Quantity

Manufacturer

Fragile

15 °C 30 °C Temperature storage limit

45% 75% Humidity storage limit

Do not use if package is damaged and consult IFU

STERILE EO Sterilized using ethylene oxide

Type BF applied part, internally powered ME equipment

Keep dry

MD Medical device

UDI Unique device identifier

Size/model

Consult Instructions for Use

Do not resterilize

Single sterile barrier system

Single sterile barrier system with protective packaging outside

Intended Use/Purpose:
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. It is intended for use during, but not limited to, general, plastic, orthopedic, and spinal surgery procedures.

Instructions Prior to Use
*Inspect sterile barrier for damage – if the sterile barrier packaging is damaged do not use and source a new device.
*Confirm activator tab 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.
*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.
*Inspect each device for damage - if device is damaged do not use and source a new device.
*Confirm expiry date prior to use - if current date is beyond the expiry date, do not use and source a new device.
*Confirm device functionality according to instructions for use - if device is defective, do not use and source a new device.

WARNING: If EtO indicator sticker is RED or if the sterile barrier packaging is damaged, contents may not be sterile. Do not resterilize.
WARNING: If used beyond expiry date, contents may no longer be sterile and may not meet essential performance. Do not resterilize
WARNING: 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 Activation: 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.
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. Manually regulate suction power using the teardrop flow control (D).
4. Use included stylet to unclog rigid suction cannula if necessary. WARNING: If device cannot be unclogged, source a new device.
5. Battery Disposal after use: Prior to disposal of device, with battery door facing downward, open the battery door by pressing on the latch (E) and by lifting the battery door away from the handle. Continue to lift the battery door until the battery falls out of the device and into the battery disposal container. Dispose of lithium primary batteries according to state and local regulations and/or facility procedures.

WARNING: Exercise caution while dissecting around the device. Direct contact with an electrosurgical instrument may cause physical damage to the device or the patient.
WARNING: 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 battery remain in patient and retrieve a new device.
WARNING: 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.
WARNING: Improper disposal of used device may lead to spread of infection.
WARNING: 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.
WARNING: 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.
WARNING: 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.
CAUTION: In case of loss of illumination during use, retrieve alternative light source.
CAUTION: Possibly hazardous optical radiation emitted from the LEDs. Do not stare at the LEDs while on as this may be harmful to the eye.
CAUTION: In extreme cases, electromagnetic disturbances may cause the light to turn OFF. To turn the light back ON, press the ON/OFF button.

With device illuminated, device provides a minimum of 180 minutes of continuous illumination. When device illumination turns off autonomously, the battery is fully depleted. Turn off light when not in use to preserve battery life.

The device is intended for use only by qualified medical personnel possessing training in the surgical procedures being performed, while in a surgical suite/operating room with a maximum operating temperature (local ambient temperature) up to 25˚C.

Indirect clinical benefit: enhanced visibility in the surgical pocket / cavity.

Device not intentionally manufactured using natural latex rubber.

Conforms to IEC 60601-1:2005,IEC 60601-1-2:2014, INTERNALLY POWERED EQUIPMENT, IPX2; CISPR 11 CLASS A, GROUP 1

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