Veinlite LEDX® <€ ĽK

DIRECTIONS FOR USE



Description

The Veinlite® LEDX is a hand-held battery powered transillumination device for visualizing veins and superficial blood vessels. It utilizes the patented* transillumination technique known as side-transillumination, which enables the Veinlite LEDX to uniformly illuminate a small region of skin and subcutaneous tissue without any areas of shadow. The shadow-free side-transillumination technique allows better visualization of veins than any other transillumination method. The LEDs emit light with the optimal wavelength for highlighting the contrast between the venous blood vessels and surrounding tissue.

INDICATIONS

Veinlite_{LEDX} TransLite

Figure 1. Veinlite LEDX

[1] Clear Window

[2] Orange Button

[4] Battery Cover

[5] Charging Socket

[3] Red Button

Intended Use/Indications

[3]

Venous access designed for sclerotherapy

- Improved visualization of veins in bariatric patients
- Specifically designed for phlebologists

Contraindications

- When used for internal examination When used without the disposable plastic cover
- Not to be used near magnetic or electromagnetic
- fields

Specifications

| Number of LEDs | 24 Orange 8 Red |
|---------------------|--------------------------|
| Weight with battery | 83g |
| Dimensions | 102 x 65 x 21 mm |
| Battery | Rechargeable Lithium Ion |

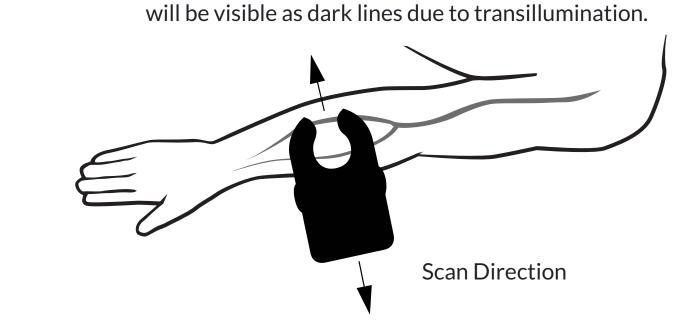
OPERATION

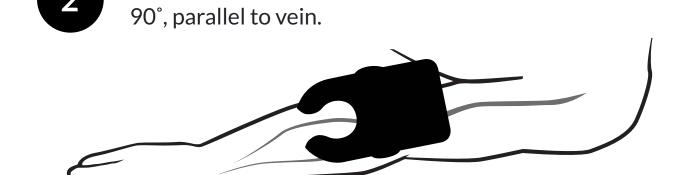
[4]

5.oV - - -

CE

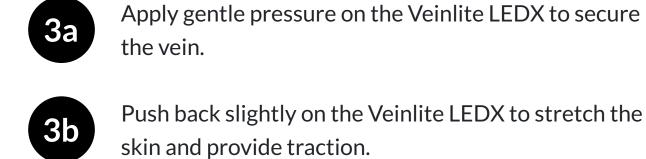
- Place the Veinlite LEDX against the patient's skin with the LED side in direct contact with the skin perpendicular to vein direction. Apply gentle pressure to maintain optimal skin contact. ■ To turn on: press appropriate button once, (located on either side
- of device), • Orange Button [2]- Small superficial veins on fair skin
- Red Button [3]- Deeper veins or darkly pigmented skin. ■ To turn off: press the selected button(s) once a second time.
- To scan for veins, place device against skin perpendicular to vein direction. Scan it forward and backward. Veins

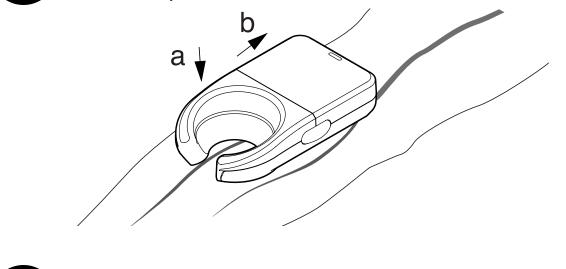


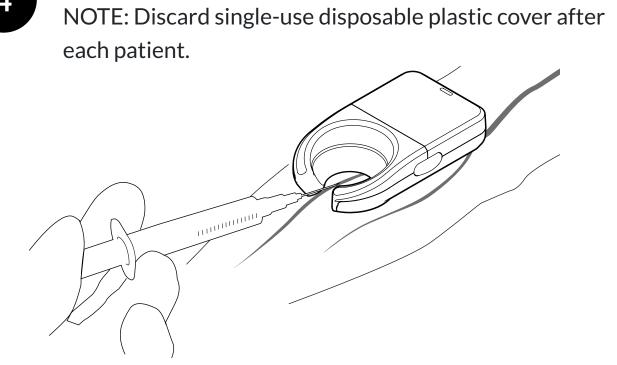


Once a suitable vein has been identified, rotate device

Access Vein







WARNING

Insert needle into vein, through the opening of device.

DO NOT SHINE THE LED LIGHTS IN THE PATIENT'S EYES.

The LEDX single-use disposable plastic covers (Product # VLEDX DPC)

USING THE DISPOSABLE PLASTIC COVERS

wipes.

MUST be used when the device comes in contact with patient's skin. CAUTION: These plastic covers are not sterile. They should be wiped with a germicidal wipe prior to use.

■ Before using Veinlite LEDX, place inside the disposable cover with the flap on the same side as the LEDs



■ Wipe the LED side of the device, and any part coming in contact with the patient, with a medically approved germicidal wipe.

Precautions Only use device with the accompanied charging cord supplied by

TransLite. ■ Do not use the device while plugged into any power source.

- Avoid using alcohol on the clear plastic window, this may cause fogging. Do not autoclave.
- Do not use liquid on the device.

WARNING

Click here to re-order LEDX disposable plastic covers. US

customers only.

Veinlite LEDX is designed for external examination only.

To avoid contamination, the LEDX must be used with disposable plastic covers.

To avoid spread of infection, always change the disposable plastic cover between patients and wipe the new cover with germicidal

LEDX is intended for use only by clinicians trained in performing vascular access, or under the supervision of a clinician.

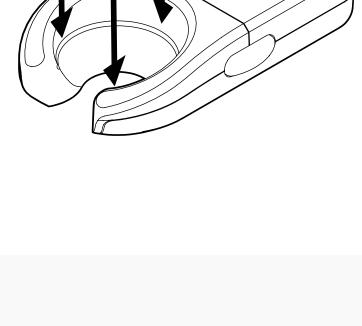
Contact Translite about adverse event in relation to this device. Should adverse event occur in E.U., notify EU Competent Authority.

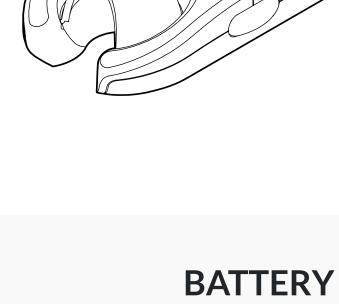
Do not look directly into LEDs while on.

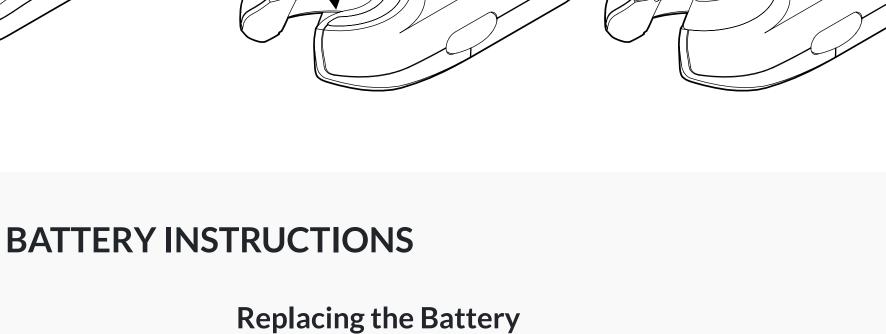
Two patented* attachments are included with the Veinlite LEDX. The diagrams below indicate how to attach the light shield and pediatric adapter. **B. Veinlite LEDX Pediatric Adapter**

A. Veinlite LEDX Light Shield Snap-on light shield reduces interference from overhead lighting. Snap-on pediatric adapter reduces the size of viewing area for use with infants.

ATTACHMENTS







orange button illuminates when the battery charge level reaches 2. Remove battery by unplugging the connector at the top.

Recharging the Battery The Veinlite LEDX is powered by a rechargeable lithium-Ion battery providing approximately 300 minutes of continuous usage.

fully charged the blinking will stop.

approximately 5% of full battery charge.

Battery Level Indicator Light

 Connect the charger by inserting it into the charging socket located on the bottom of the device (5).

■ The orange button will blink indicating device is charging. Once

Veinlite LEDX incorporates a low battery level indicator light. The

3. Replace the battery with a new battery by plugging it into the connector.

1. Slide off battery cover.

4. Slide battery cover back on.

https://www.veinlite.com/faq

- NOTE: Before using your Veinlite LEDX. please read the detailed battery safety information on our website FAQ page:

WARRANTY INFORMATION The Veinlite LEDX has a one-year parts and labor warranty. The warranty is valid only if the device is used according to the manufacturer's instructions. Before returning the device to Translite for repair, you must call or e-mail to obtain a return authorization code and shipping information. Please

provide the serial number located under the battery or outside the box when contacting the manufacturer. No refunds for unauthorized shipping.

EXPLANATION OF SYMBOLS

Temp -20C/68F to +50C/122F



Humidity 45-80%

Ireland

REF Model Number

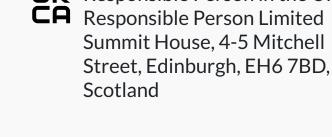
SN Serial Number

5 Fitzwilliam Square East **Dublin 2 DO2 R744** Tel: +353 89 225 1951 info@ecrep.ie

* This product is covered by Patents. Patent

Numbers: 7,874,698; 7,841,751; 8,032,205;

8,177,808



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2 Do Not reuse

Consult instructions for use

