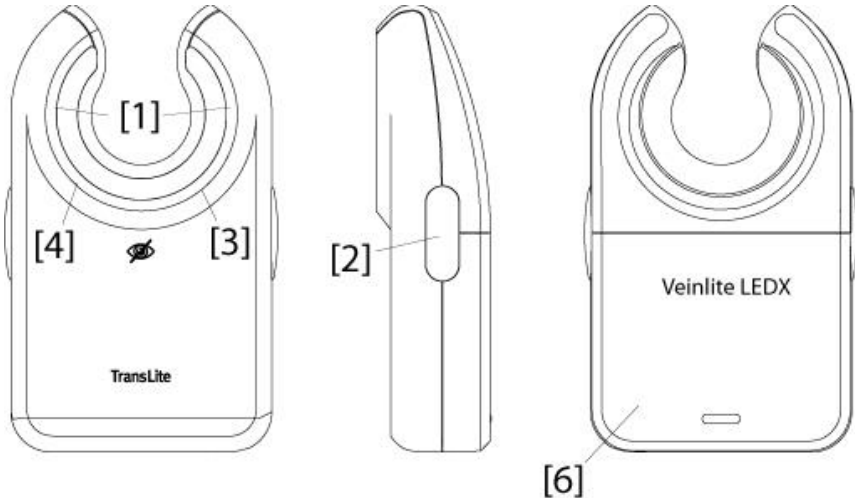
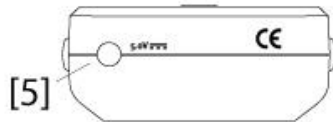


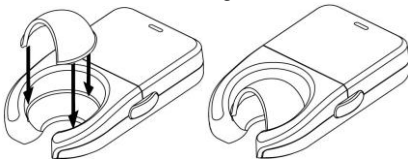
Veinlite[®] LEDX CE



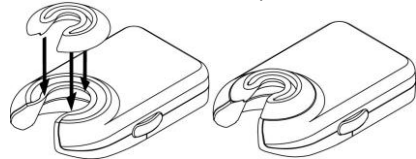
- [1] Clear Window
- [2] On/Off Button - Low Battery Indicator
- [3] Red Charging LED
- [4] Green Charging LED
- [5] Charging Socket
- [6] Battery Cap



Veinlite LEDX Light Shield



Veinlite LEDX Adapter



READ INSTRUCTIONS BEFORE USE

CAUTION:

- Veinlite LEDX is designed for external examination only.
- Do not use Veinlite LEDX without the disposable plastic covers.
- To avoid cross contamination between patients, always change the disposable plastic cover between patients.
- Do not look directly at the LEDs when they are illuminated or shine the light from them directly into anyone's eyes.

INSTRUCTIONS

Introduction

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 orange LEDs emit light with the optimal wavelength for highlighting the contrast between the venous blood vessels and surrounding tissue*.

Applications

- Visualizing and mapping varicose veins, prior to and during vein treatment
- Aiding venous access in pediatric and adult patients, especially those with a history of difficult venous access
- Easier visualization of veins in darkly pigmented patients
- Easier visualization of veins in overweight and obese patients

Description of the Veinlite LEDX

The Veinlite LEDX has 32 light emitting diodes (LEDs), mounted in a circular array and angled towards the center of the circle. 24 LEDs emit orange light and 8 LEDs emit red light. The light from the LEDs shines through a clear plastic window [1] so that it is focused under the skin. There is an opening in the circle to allow access.

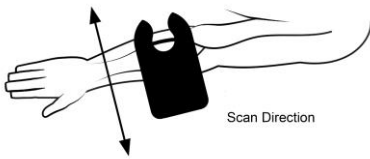
The light from each set of LEDs has specific characteristics selected for optimal vein visualization at varying depths and through skins of different tones. The properties of the orange light are optimal for viewing superficial veins (including small varicose and spider veins), whereas the properties of the red light are optimal for viewing deeper veins. The red light also provides better penetration through darker skin.

Each set of LEDs can be independently selected by pressing one of two separate buttons [2] located one on each side of the Veinlite LEDX. The orange LEDs are controlled by the orange button and the red LEDs by the red button. Both sets of LEDs can be switched on at once by pressing both buttons at the same time.

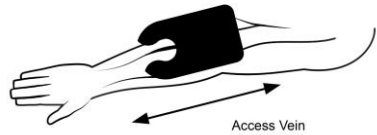
Operating Directions

1. Place the Veinlite LEDX inside the single-use disposable plastic cover. Wipe the area of the cover coming in contact with the patient with an alcohol swab or germicidal wipe.
2. Turn off any fluorescent lights that are directly overhead, as these may interfere with the transillumination. Working under non-fluorescent side lighting is optimal.
3. Place the Veinlite LEDX against the skin with the LED side in contact with the skin.
4. Depress the orange and/or the red button/s [2] to turn on the LEDs.
5. Apply gentle pressure to the Veinlite LEDX to ensure it is in contact with the skin.
6. Use the orange button only if you are examining small superficial or spider veins. Use the red button also if you are examining deeper or feeder veins or if the skin is darkly pigmented.
7. To access a vein while viewing with the Veinlite LEDX, place the Veinlite LEDX over the vein. Rotate the opening in the Veinlite LEDX so that it faces away from the heart (see diagrams on next page).
8. Apply gentle pressure on the Veinlite LEDX to sequester the vein. Push back slightly on the Veinlite LEDX to stretch the skin and provide traction. Insert the needle into the vein in the normal way, through the opening in the circle of LEDs.
9. Discard the single-use disposable plastic cover after each patient.

10. The Veinlite LEDX may be cleaned periodically with a germicidal wipe but wiping the unit should be done in addition to using a new disposable plastic cover for each patient.



Position of Veinlite LEDX while looking for vein



Position of Veinlite LEDX while accessing vein

Disposable Plastic Covers

The single-use disposable plastic covers for the Veinlite LEDX must be used whenever the Veinlite LEDX is placed in contact with a patient's skin. The covers protect the Veinlite LEDX from contamination and prevent cross contamination between patients. These plastic covers are not sterile. Before using Veinlite LEDX, place it inside the cover with the flap on the opposite side of the Veinlite LEDX from the LEDs. When it is inside the cover, wipe the LED side of the Veinlite LEDX, and any part of it coming in contact with the patient, with a medically approved germicidal wipe. The Veinlite LEDX is shipped with a pack of 50 plastic disposable covers. Additional packs can be ordered from TransLite or its authorized dealer.

Low Battery Level Indicator Light

The new Veinlite LEDX incorporates a low battery level indicator light located in the orange light push button [2]. The light is activated when either the orange or the red lights are turned on and the battery charge level has fallen to approximately 20% of the full battery charge.

Recharging the Battery

The Veinlite LEDX is powered by a rechargeable lithium ion battery similar to a cell phone battery. This battery is designed to provide between 130 and 160 minutes of continuous usage, depending on whether one or both sets of LEDs are used at once. The Veinlite LEDX battery must be recharged by plugging the metal pin of the Veinlite LEDX battery charger into the charger opening in the Veinlite LEDX [5], then plugging the charger into a power outlet. A red LED light [3] can be seen in the clear window [1] when charging the battery and a green LED light [4] can be seen when it is fully charged.

**DO NOT ATTEMPT TO CHARGE THE VEINLITE LEDX WITH ANOTHER CHARGER!
USING ANOTHER BATTERY CHARGER WILL DAMAGE THE VEINLITE LEDX.**

Replacing the Battery

The rechargeable lithium ion battery in the Veinlite LEDX is capable of over 500 charging cycles (typically approximately three years of use) before it requires replacement. Battery replacement is simple. Slide the battery cap [6] off and lift out the battery. Unplug the connector at the top of the battery. Replace the battery with a new battery and plug in the connector. Slide the battery cover back on. Before using your Veinlite LEDX, please read the detailed battery safety information on our website FAQ page <http://www.veinlite.com/faq>.

USE ONLY THE VEINLITE LEDX BATTERY FROM TRANSLITE.

Cleaning Directions

Wipe the device with a damp cloth. Always use the disposable plastic covers to protect the device and to minimize the spread of infection. Whenever necessary, the Veinlite LEDX should be cleaned using a germicidal wipe or other medically accepted disinfectant.

DO NOT AUTOCLAVE THE VEINLITE LEDX! DO NOT IMMERSE IT IN ANY LIQUID!

Troubleshooting

Before returning the Veinlite LEDX to TransLite for repair, please call or e-mail to obtain a return merchandise number and shipping information. No refunds for unauthorized shipping.

- LED Failure

The light source contains LEDs designed to have an excess of 100,000 hours of operation. They should not require replacement during the life of the Veinlite LEDX. If an LED fails, the unit is designed to continue operating using the remaining LEDs, with only a slight decrease in intensity of light output. In case of multiple LED failure, please contact TransLite to arrange return for repair. Do not attempt to replace any LEDs.

- No Light from any LEDs

Recharge the battery. During charging, make sure the red light [3] comes on to indicate that the battery is charging and the green light [4] comes on to signal that the battery is fully charged. If the red light does not stay on, reseal the battery plug in the unit. In the event that the battery is fully charged but the unit does not turn on, call TransLite for assistance.

- Battery Fails to Charge

If the battery fails to charge and the Veinlite LEDX is over two years old, please replace the battery with a new one. You can order a replacement battery from TransLite via our web site, www.veinlite.com, or by calling TransLite or its authorized dealer.

Warranty

The Veinlite LEDX has a one year parts and labor warranty. It is not necessary to register your Veinlite LEDX for warranty: the process is automatic and the serial number of the unit provides all the information needed.

Veinlite LEDX Specifications

Number of LEDs: 24 orange and 8 red LEDs

Weight Including Battery: 83g

Dimensions: 102 x 65 x 24 mm




Field of View Diameter: 31mm

Access Opening: 17mm

Rechargeable Battery: 3.7V, 1000 mAh Lithium Ion

Battery Charger: 90-240 volts AC input, 5 volts DC output

Explanation of Symbols

| Symbol | Explanation |
|---|---|
| REF | Model Number |
| SN | Serial Number |
|  | Manufacturer |
|  | EC Representative (EU Only) |
|  | Do not dispose as unsorted municipal waste. |

| | |
|----|-----|
| EC | REP |
|----|-----|

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*US Patent No.: 5,146,923
*US Patent No.: 7,874,698B2

VLEDX DFU 0514

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