Directions for Use

Veinlite® II

TransLite, LLC

IMPORTANT: Veinlite® II is a device which allows the medical practitioner to better visualize superficial veins. This information should be incorporated with the patient history, and other examination information, to aid the physician in making a diagnosis. Veinlite data should not be used as the only basis for making a clinical diagnosis of vein disease.

Veinlite uses the same side-transillumination design as the Nevoscope which has US Patent No. 5,146,923. Several other patents are pending.

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2. Introduction

Veinlite II uses a new transillumination technique, called side-transillumination, to achieve much better imaging of veins, anywhere on the body.

Veinlite II's ring illuminator design allows uniform transillumination of a small region of the skin, without any shadows.

Superficial veins that are less than 6 mm deep can be seen as dark shadows in a bright background. Visualization of these veins is determined by the type of light used and the properties of the skin, which absorbs shorter wavelength light (blue and green) and transmits longer wavelength light (orange and red).

3. Description of Veinlite II illumination technique

Veinlite II is a new imaging device that uses the same patented side-transillumination technique as the Nevoscope*. Side-transillumination is a technique whereby a ring of bright fiber optic light is directed into the skin, at an angle such that the light is focused under the skin. The focused light creates a virtual light source under the skin, uniformly transilluminating the skin inside the ring light opening. Veins are seen as dark lines against a bright background.

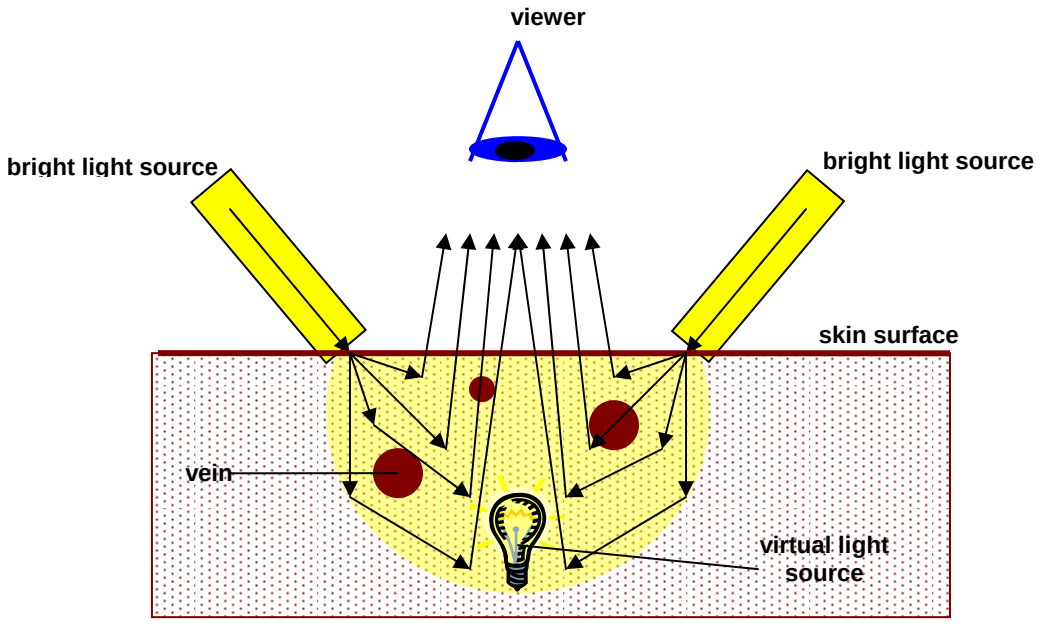

Figure 1. Side-transillumination

*Veinlite uses the same patented side-transillumination technique used in the Nevoscope, which has US Patent Number 5,146,923.

4. High contrast (HC) imaging with orange light

Veinlite II has a patent pending method of highlighting superficial veins by the use of narrow band orange light. A special filter built into the light source unit can be used to deliver narrow band orange light. A filter switch, located on the front panel of the Veinlite II light source, allows the user to select either white light or narrow band orange light. The white light option delivers a light spectrum similar to the original Veinlite fiberoptic transillumination devices that have become standard for superficial vein imaging. Narrow band orange light is absorbed more completely by deoxygenated hemoglobin in veins than is white light. Therefore, using the narrow band orange filter, superficial veins appear darker than they do with white light and the contrast between the vein and surrounding tissue is greater. The pictures below, of a superficial varicose vein, show the difference between white light imaging and high contrast (HC) imaging.

The two photographs below are courtesy of VNUS® Medical Technologies, Inc.

Figure 2. White light image of varicose veins with Veinlite II

Figure 3. HC imaging of varicose veins with Veinlite II using orange light

5. Operating Instructions

Veinlite II comprises a 150 watt halogen light source with EJA or EKE type halogen bulb and a 6ft flexible fiberoptic cable attached to the patented ring illuminator.

Please review the image of the light source on the first page when reading the following description of the control switches.

The power switch is located on the front panel of the light source. In addition to switching on or off, the power switch also controls the illumination level. Turning the switch in a clockwise direction switches the light on and continuing to turn clockwise increases the light intensity. Turning the switch counter-clockwise decreases the light intensity and continuing to turn clockwise switches the light off.

Also located on the front panel is the filter switch to select or de-select the narrow band orange filter. Turning the filter switch to the orange setting places the narrow band orange filter in the light beam, enabling HC imaging. Turning the filter switch to the clear setting removes the orange filter from the light beam, enabling white light imaging.

The metal connector at the straight end of the ring illuminator cable fits snugly into the round opening on the front panel of the light source. The ring illuminator end should be inserted into this opening before the light is switched on. Light is channeled through the fiberoptic cable to the ring illuminator which directs the light under the skin.

Disposable plastic covers are supplied with the ring illuminator. The covers are for single use only and should be discarded after each patient. The ring illuminator should be placed in a disposable cover, then the cover should be wiped with 70% alcohol, chlorhexidine or other approved decontamination solution.

- To use the Veinlite II for visualizing veins, first turn off overhead fluorescent lights which interfere with transillumination. Use non-fluorescent side lighting instead of the overhead fluorescent light.
- Put the Veinlite II ring illuminator in the disposable plastic cover then wipe the cover with 70% alcohol or other approved decontamination solution.
- Visually locate the approximate region of interest of the skin and then position the ring light over it.
- Always turn the illumination level down to a minimum before turning on the power to the light source. This minimizes transient power surges that can destroy the filament of the halogen bulb.
- Always use the lowest light intensity while positioning the ring light on the skin. Once positioned, the intensity can be adjusted to the desired level.
- Intense orange light is optimal for visualizing small surface veins.
- Less intense white light level is useful for visualizing deeper veins.
- Apply gentle pressure to the ring to ensure it is in contact with the skin.

CAUTION: Do not look directly at the ring illuminator when the light is on.

6. Care and Maintenance

6. (a) Cleaning Instructions

CAUTION: Always turn the light source off and disconnect the power cord before cleaning the Veinlite II.

- Use the disposable plastic covers provided to avoid contaminating the ring illuminator.
- Wipe the cover with 70% alcohol after the ring illuminator is placed in the cover.
- Discard the cover after each patient.
- Clean the ring illuminator with 70% alcohol or other medically accepted cleaning solution.
- The light source unit and fiberoptic cable may also be cleaned using 70% alcohol or other medically accepted cleaning solution.
- The Veinlite II is water resistant but not waterproof.
- Do not use abrasive material on any part of the equipment or immerse the device in liquid.
- The Veinlite II ring illuminator is autoclavable.

6. (b) Light Source and Halogen Bulb

CAUTION: Do not look directly into the light.

The light source contains a halogen light bulb that has a limited life-time.

- Use the power switch on the front of the light source to control the light level.
- Always turn the light source off when not in use.

Replacement of the halogen light bulb should be carried out with extreme caution.

- Only EJA or EKE type 150W 21V halogen bulbs must be used in the Veinlite II.
- Always disconnect the light source unit from the AC power supply before changing the bulb.
- Always allow the unit to cool down for at least an hour before changing the bulb.
- Do not touch the inner surface of the replacement bulb.
- Use a screwdriver to loosen the large screw on top of the light source unit, then pull up the top cover plate and swing it backwards to access the interior.
- Push the small lever (next to the light bulb) backwards to raise the bulb slightly out of the metal clamp which holds it in place.
- Gently remove the bulb from the holding clamp and disconnect the plug from the back of the bulb.
- Position a new EJA or EKE type bulb in the clamp and reconnect the plug.
- Push the lever back to its original position so that the bulb will be properly positioned for illuminating the fiber optic cable.
- Replace the top cover of the light source unit and fasten the screw on the top of the box before reconnecting the unit to the AC power supply.

7. Veinlite II Specifications

The Veinlite II model comes with a large ring illuminator which is specially designed for mapping larger veins and finding reticular veins. The large ring illuminator has a wide opening to facilitate injections or use with lasers during sclerotherapy treatment.

Figure 4. Large ring illuminator with wide opening

Veinlite II (product code VL II) specifications

Input Voltage	115V, 60 Hz AC
Light Source Power	150 Watts
Power Output Adjust	Rheostat continuously variable
Halogen Bulb Type	EJA (EKE type bulb may also be used)
Color Temperature (approximate)	3250 degrees (max intensity with EJA bulb)
Filter Options	No filter/narrow band orange filter
Fiberoptic Cable Length	6ft
Ring Top Diameter (outer)	62 mm
Ring Top Diameter (inner)	51 mm
Ring Bottom Diameter (inner)	36 mm
Fiber Taper Angle	36 degrees
Light Window Width	0.5 mm
Disposable Plastic Covers	50 per pack, re-order code VLII-DPC
One Year Warranty	Covers all parts, excluding halogen bulb