Safety tips for intense pulsed light therapy

U.S. Food & Drug Administration

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DEVICE SAFETY INTENSE PULSED LIGHT (IPL) therapy is indicated for use in surgical, aesthetic, and cosmetic applications.[1] IPLs use flashlamps, computercontrolled power supplies, and bandpass filters to generate light pulses of prescribed duration, intensity, and spectral distribution. The light energy is converted to heat energy to treat skin conditions such as age spots, sun-damaged skin, cutaneous lesions (such as warts, scars, and striae), benign pigmented epidermal lesions (such as freckles and melasma), and vascular lesions (such as spider veins).[2-4] It's also commonly used to reduce undesired hair growth.

This noninvasive and nonablative treatment uses many wavelengths or colors of light. In contrast, lasers use only one wavelength. IPL zeroes in on the dermis without affecting the epidermis.[4]

Although IPL is safe and effective when clinicians follow the manufacturer's instructions for using and properly maintaining the equipment, complications have been reported when these measures weren't taken. The FDA has received adverse event reports of burns, blisters, scarring, and skin discolorations. One of the main factors contributing to these complications was the failure to adhere to the device's operation and maintenance instructions.

What went wrong?

The FDA received several reports of patients sustaining second-degree burns after IPL therapy. The manufacturer's investigation of those reports determined the probable root cause for the adverse events to be improper device calibration or failure of the user facilities to clean the device as directed in the device labeling.

What precautions can you take?

Adhere to the instructions provided by the manufacturer when using or cleaning an IPL device.

- Check the device's calibration before every use or as often as recommended by the manufacturer.
- If a problem with device calibration occurs, contact the manufacturer for service. Don't use the device until calibration can be confirmed.
- Follow the manufacturer's device specific cleaning directions. Different parts of the system may require cleaning with different methods.

- Contact the device manufacturer if you have any questions about maintaining and cleaning the device.

Additional nursing considerations

- Ask your patients if their skin's appearance is their natural one or if it's due to intentional tanning, unintentional sun exposure, or any other reason. Light reacts differently on different skin colors. To treat the same condition, clinicians use different levels of light energy for patients with different skin colors.
- Ask your patients about the medications they're taking and inform the clinician if a patient is taking a medication that causes photosensitivity. The patient should avoid IPL treatment because it could cause an undesired effect.
- Make sure your patient has followed pretreatment preparation instructions. Make sure he or she has given informed consent.
- Teach your patient IPL posttreatment skin-care regimens according to the indication or purpose of the IPL treatment rendered.
- Make sure your facility's devices have been cleared or approved by the FDA to treat the conditions for which they're being used.

REFERENCES

1. U.S. Food and Drug Administration. Premarket Notifi cation 510(K) Number 030342. Lumenis Ltd. Family of IPL Systems and Combination IPL/ND:YAG Systems. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=10785. [1]
2. Lumenis Aesthetic. Intense pulsed light (IPL). http://www.aesthetic.lumenis.com/ipl.
3. Habif TP. Clinical Dermatology: A Color Guide to Diagnosis and Therapy. 5th ed. Edinburgh: Elsevier Mosby; 2010.
4. New Zealand Dermatological Society. Intense pulsed light therapy. DermNetNZ. 2009. http://dermnetnz.org/procedures/ipl.html [2].

RESOURCE

Dermatology Nurses' Association. The nurse's role in the use of laser, light, and energy emitting devices. http://www.dnanurse.org/nurses-role-use-laser-light-and-energy-emitting-devices [3].

Although you need to support your healthcare facility's adverse event-reporting policy, you may voluntarily report a medical device that doesn't perform as intended by contacting MedWatch at 1-800-FDA-1088 (fax 1-800-FDA-0178) or online at http://www.fda.gov/Safety/MedWatch/HowToReport. [4]

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SOURCE [5]

Links:
[1] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=10785
[2] http://dermnetnz.org/procedures/ipl.html
[3] http://www.dnanurse.org/nurses-role-use-laser-light-and-energy-emitting-devices
[4] http://www.fda.gov/Safety/MedWatch/HowToReport
[5] http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm294084.htm