

Physicians warned about counterfeit medical devices

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Physicians should be aware of the prevalence and serious consequences associated with use of counterfeit medical devices, according to a letter to the editor published online July 20 in *Lasers in Surgery and Medicine*.

(HealthDay)—Physicians should be aware of the prevalence and serious consequences associated with use of counterfeit medical devices, according to a letter to the editor published online July 20 in *Lasers in Surgery and Medicine*.

Brian S. Biesman, M.D., from the Nashville Center for Laser and Facial Surgery in Tennessee, and Neelam Patel, from the Vanderbilt University School of Medicine in Nashville, discuss the prevalence and dangers of counterfeit medical devices, many of which target legitimate devices manufactured by Zeitiq and Ulthera.

The researchers note that both companies' devices are protected by patents and have integrated safety features. However, the counterfeit



devices are not certified as safe, reliable, or reproducible, and numerous injuries have been documented with their use. There may be economic incentives for purchasing counterfeit devices, but these are outweighed by the risks and liabilities associated with using counterfeit technology. Medical malpractice insurance carriers may not provide coverage for litigation arising from use of non-U.S. Food and Drug Administration-approved devices. There are currently 29 imitations of the Zeltiq device and at least five counterfeit Ulthera devices. Despite being unregulated and unapproved, these can be purchased via the Internet and some are displayed at legitimate trade shows.

"Physicians should be aware of the existence and prevalence of counterfeit <u>medical devices</u> and need to understand that use of these devices in the United States can lead to severe economic, civil, and criminal penalties," the authors write.

One author disclosed financial ties to Zeltiq and Ulthera.

More information: Full Text

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