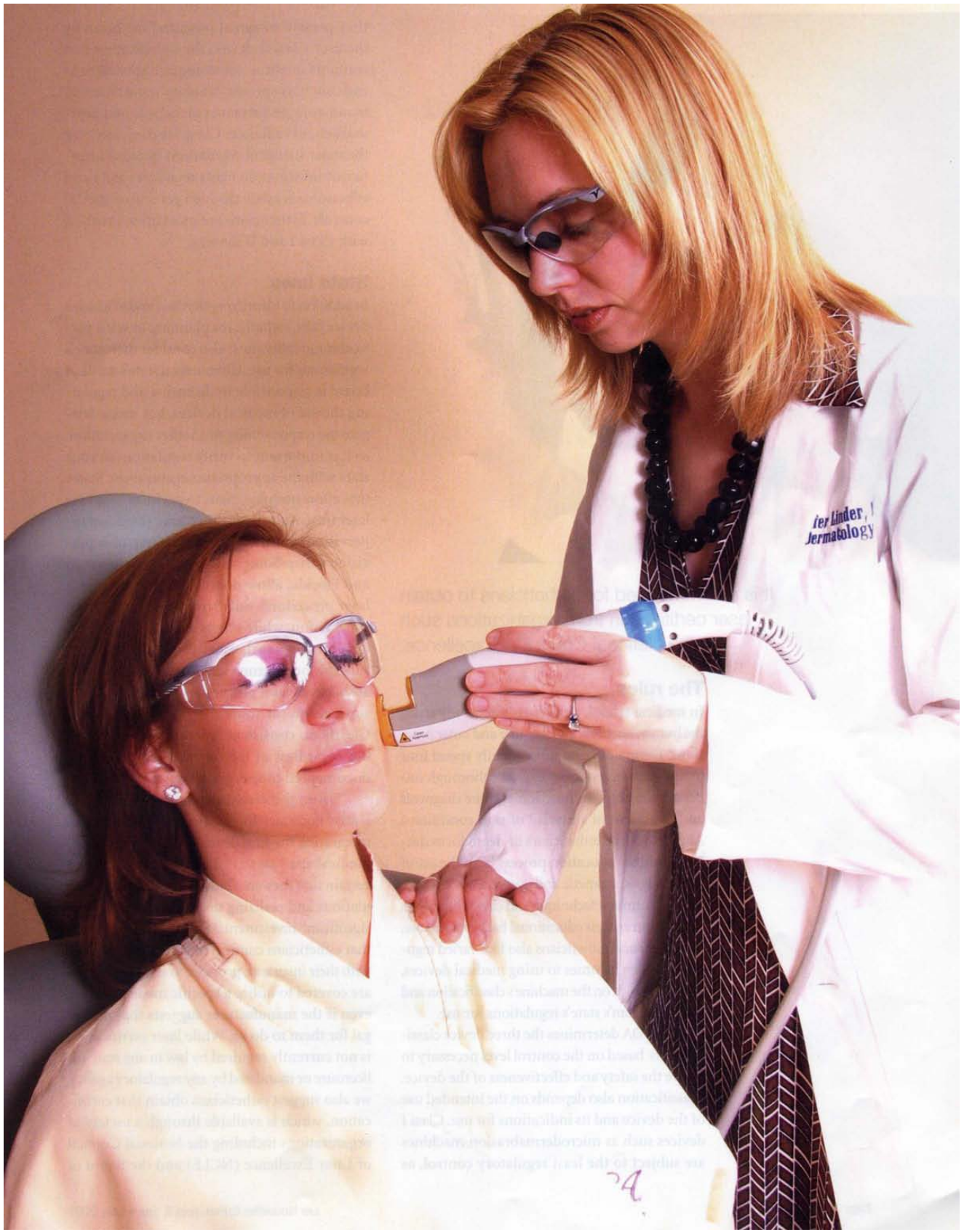


Maximizing Medical Devices

VIEWS FROM THE DERMATOLOGIST AND ESTHETICIAN

BECAUSE of the increasing demand for cosmetic procedures, estheticians are integrating medical modalities into their businesses to maximize profits. Physicians are also seeking ways to incorporate these devices into their practices. Because legal regulations vary between estheticians and medical professionals, and from state to state for the use of medical devices, it can be confusing for professionals who want to purchase these devices to use as a part of their clients' treatment plans. With the help of dermatologist Jennifer Linder, M.D., and my esthetics experience of more than 20 years, this article aims to demystify the rules and help doctors and estheticians better understand the benefits of working together to achieve the best results for their clientele. ➔

by Margaret M. Ancira with Jennifer Linder, M.D.





It is recommended for estheticians to obtain laser certification from organizations such as the National Council of Excellence.

The rules

In medical school, physicians extensively study the human anatomy and its inner and outer functions. Dermatologists subsequently spend four to five years in residency to gain a thorough understanding of skin function and the diagnosis and treatment of a myriad of skin conditions. Alternatively, an esthetician's in-depth focus during his or her education process is on the art of skin analysis, cosmetic and cosmeceutical ingredients, treatment technique and client follow-up. As different as their educational backgrounds are, physicians and estheticians also face varied regulations when it comes to using medical devices, which depends on the machine's classification and the esthetician's state's regulations for use.

The FDA determines the three device classifications based on the control level necessary to assure the safety and effectiveness of the device. Classification also depends on the intended use of the device and its indications for use. Class I devices such as microdermabrasion machines are subject to the least regulatory control, as

they present minimal potential for harm by the user. Class II device, the classification that contains medical lasers, require special controls such as specific labeling requirements, mandatory performance standards and post-market surveillance. Class III devices carry the most stringent regulations because insufficient information exists to assure safety and effectiveness solely through general or special controls. Estheticians are most often involved with Class I and II devices.

State laws

In addition to identifying the class under which a device falls, estheticians planning to use a particular modality must also consider their state's regulations for use. Ultimately, a state's medical board is responsible for licensing and regulating the use of medical devices, but many delegate the responsibility to another organization, so it is important to verify regulations in your state with the appropriate organization. States that allow nonphysicians to perform cosmetic laser treatments typically require physician supervision, but the necessary degree of supervision varies. Some states, including Colorado and Florida, allow nonphysicians to perform laser procedures only with on-site physician supervision, while others such as Illinois and Oregon, allow such use with off-site physician supervision. Arizona and Kentucky differentiate between laser procedures, requiring on-site supervision for some and off-site for others. Clearly no consistent federal standard exists, but regardless of the supervisory guidelines, documented training is always required.

"Given the varied regulations, research is always necessary for physicians or estheticians integrating medical devices in their practice or medical spa," says Dr. Linder. "They must be certain that they are abiding by their state's regulations and realizing the full potential of this significant investment." She also recommends that estheticians confirm their liability coverage with their insurance provider to ensure that they are covered to utilize a specific medical device, even if the manufacturer suggests that it is legal for them to do so. While laser certification is not currently required by law in any state for licensure or mandated by any regulatory agency, we also suggest estheticians obtain that certification, which is available through a variety of organizations including the National Council of Laser Excellence (NCLE) and the Board of

Laser Safety. We believe that obtaining this professional credential reflects your knowledge and professionalism in the field and lends credibility to your practice. Additionally, the prerequisite training requirements to receive this certification frequently meet regulatory or state licensing requirements.

In the doctor's office

Vein treatment, hair removal, skin rejuvenation and resurfacing are just a few of the procedures performed in physicians' offices and medical spas that require the use of medical devices. These modalities can include any or all of the following: microdermabrasion, ultrasound, light emitting diode (LED) or photo facial rejuvenation, intense pulsed light (IPL), photodynamic therapy (PDT) and laser. There is a delicate balance between the doctor's role and that of the esthetician in the use of these machines. Not only must FDA regulations be considered, but the patient's needs and the type of facility must be properly assessed. Dr. Linder and I agree that the best results come from the doctor and the esthetician working in tandem, each contributing their own expertise to the overall treatment plan, which may include any combination of chemical peels, procedures with noninvasive or invasive medical devices, home care products and either oral or topical pharmaceuticals. We believe this type of collaboration is the most cost-efficient and effective scenario for both patients and professionals: the physician's time is best utilized, patients get the best combination of medical and esthetic attention, and the use of the office space is maximized.

When a patient is visiting a physician's office or medical spa to address a skin condition, certain steps should be followed to ensure they receive the safest, most effective treatment regimen to produce favorable results. To begin, a thorough consultation and skin analysis is necessary. With expertise in this area, estheticians in many cases can make assessments and recommendations for treatment. Oftentimes, the patient will desire a more dramatic outcome than what they may experience from a procedure such as microdermabrasion alone. Some treatments can be safely enhanced when used in conjunction with other devices or properly blended chemical peels and customized home care regimens. But it is the esthetician's role to inform patients when a more advanced treatment or combined modalities might not be right for them, even if they express the desire for more immediate

visible results. After the patient's condition has been assessed and the appropriate treatment regimen decided upon, the esthetician should explain any procedures that will be performed and discuss pre- and post-treatment skin care, as well as proper home care and future preventive measures for the condition, such as the daily use of a broad-spectrum sunscreen.

Doctor involvement

Sometimes the physician will need to take a more active role in a patient's treatment. Dr. Linder strongly advises that if more advanced diseases are presented, such as grades III and IV acne or polycystic ovary syndrome, the esthetician should consult the physician before making recommendations. This is especially important when advanced protocols are to be a part of the treatment plan to avoid any possible complications for the patient. Depending on the case, the doctor might want to do the initial consultation and then check in during treatment or follow

continues

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up with the patient after a procedure. For even more significant conditions, it is at the physician's discretion to perform any necessary procedures and prescribe oral or topical medications. In a medical spa, it is important for the esthetician to consult the medical director. Dr. Linder believes estheticians should also have a relationship with a dermatologist they can consult with or refer to before proceeding to treat more difficult types of conditions such as unusual or suspicious skin lesions or rashes.

Using machines

When nonphysician use of medical devices is allowed, Dr. Linder suggests doctors set boundaries and put procedures in place for treatments. She also recommends physicians outline protocols for each treatment and device they offer and properly prepare their staff for every possible situation. The success of this arrangement according to Dr. Linder relies on the proper training and education of estheticians and registered nurses in the use of the devices. And estheticians should seek doctors to work with who are willing to provide them with this knowledge.

"Education is the key in being able to operate medical devices properly and to have the ability to assess the risks, benefits and potential treatment complications that go along with them," she says.

She advises that skin care professionals who add advanced devices and treatments to their esthetics practice seek continuing education at various national conferences and courses throughout the year. They should also select a clinical skin care company that offers skin biology and medical modalities seminars on the safest and most effective ways to combine various medical devices, professional treatments and home care regimens.

The first step in mastering medical modalities is to develop a deeper understanding of how the skin functions and its response to external forces from either a medical device or a topical product. Treatment is only as safe and effective as the technician's knowledge of the application, whether it involves a topical product or a mechanical device. In addition to the physician providing knowledge to the esthetician, it is imperative that the two have a good working relationship and that the lines of communication remain open in order for the practice to succeed. Neither medical nor skin care professional should push the boundaries when working with mechanical devices as a part of their patients' skin care regimens. In consideration of patient safety, ethical boundaries and running a successful business, knowing legal limitations, proper patient screening and education, and advanced training are all necessary elements for any esthetics practice that uses medical modalities alone or in combination with other treatments and products. ■

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Margaret Ancira is the founder of PCA Skin. A licensed esthetician, Ancira helped create PCA's innovative formulations including chemical peels. She is a published author who has lectured in Asia, Europe and Latin America, and is a regularly featured speaker at major medical and esthetics industry conferences across the United States. For more information, visit www.physchoiceaz.com.



Dr. Linder and Ancira