When Deciding on a HAIR RESTORATION LASER for Your Practice, You Need to Address the Important Points

With several options on the market for the promotion of hair growth for both men and women with androgenic alopecia, how do you decide which device is best suited for your practice?

Most physicians agree that in order to recommend the best course of treatment for the patient, a light therapy device should be safe, proven and convenient, in order to produce the natural hair growth results your patients seek. Products on the market range from combs to helmets, over -the-counter to prescription, and vary in price, compliance and efficacy. Here is some advice on how to evaluate what laser device best suits the needs of your patients.

DOES THE DEVICE MEET REGULATORY REQUIREMENTS?

Essential to the decision to recommend a particular device to patients should be whether or not the device is regulated. It is critical to determine whether the manufacturer has undergone the regulatory requirements for patient safety and whether it has been granted the authority for legal distribution. If a medical device manufacturer has not been registered and processed through the proper regulatory channels, selling or distributing the device may mean jeopardizing patient safety and acquiring liability for doing so.

At Capillus, we are committed to meeting regulatory requirements. The Capillus272 meets the following regulatory standards: 21 CFR 1040.10 laser safety & labeling, IEC 60825 laser safety and classification, IEC 60601 EMC/EMF standards.

IS THE DEVICE CLEARED BY THE FDA?

A 510(k) is a premarket notification made to the FDA to demonstrate that a device is safe and effective for its intended use. Clearance is achieved based on an application by the manufacturer of the device to the FDA. This application may include clinical studies that prove efficacy, as well as safety information, and other evidence showing that the device has been deemed safe and effective for its intended use.

The Capillus272 has been cleared by the Food and Drug Administration by a 510(k) for the promotion of hair regrowth in adults with androgenic alopecia (AGA) having Ludwig Savin classifications I-II or Norwood Hamilton classifications of IIa-V and Fitzpatrick Classification of Skin photo-types I-IV.

HAS THE DEVICE UNDERGONE CLINICAL TRIALS?

When submitting a premarket application for clearance to the FDA, a manufacturer may submit clinical trial results conducted for the device. By visiting the federal website www.clinicaltrials.gov, physicians can search the status of any given device. Devices claiming to be participating in clinical trials should be registered as required by the Safe Medical Device Act of 1996.

The Capillus272 clinical trial was registered on ClinicalTrials.gov and was managed by a neutral third party. The clinical trial data indicated that low-level laser treatment of the scalp every other day for 17 weeks with the Capillus272 device, significantly improved hair counts by 51% in those study participants who used the active (non-placebo) device. Subjects were able to use the device on a self-treatment home-use basis and no adverse events or side-effects were reported. The Capillus272 was proven to be a safe and effective treatment for androgenic alopecia.

IS THE MANUFACTURER REGISTERED AS A MEDICAL DEVICE MANUFACTURER WITH THE FDA?

Another consideration is whether the company is registered as a medical device manufacturer. In the USA, any manufacturer of an FDA-cleared medical device is required to register with the FDA as a new device establishment within 30 days of clearance. You can search the medical device databases registration listing on the FDA website.

Capillus is a registered device manufacturer with the US Food and Drug Administration.

IS THE DEVICE THE BEST LASER FOR HAIR LOSS TREATMENT YOU CAN OFFER PATIENTS?

The effectiveness of a product is only as good as the compliance of its use. In order for any product to work as it promises, it must be used as indicated. It should be easy and comfortable to use, non-disruptive to a patient's lifestyle, and deliver on results.

Many hair restoration physicians prefer the Capillus272 laser therapy cap because its convenience encourages patient compliance. Patients can wear it for half an hour every other day, without disrupting their lifestyles. It is uses a power pack so patients can wear the cap while they cook, watch TV, go for a walk, etc. It requires no user effort during operation. With 272 laser diodes, the Capillus272 device features more lasers than any laser device for hair loss treatment with FDA clearance, providing maximum laser coverage of the affected areas of hair loss.

WHERE IS THE PRODUCT MANUFACTURED?

Many devices in the market are manufactured abroad. While this may allow for lower costs and subsequently lower pricing, it diminishes the control the manufacturer has over the quality of the product being made.

At Capillus, we are proud to say that each one of our units is now hand-made in the USA, allowing complete control of the quality of our product. Every single unit is inspected before shipping according to our quality system to ensure that each product that leaves Capillus meets regulatory standards, as well as those placed on ourselves to meet the needs of our customers. We stand behind our product with a 3 year warranty on the device, giving patients peace of mind. All repairs are handled by our service technicians in our Miami, Florida headquarters. Manufacturing in the USA also gives us more flexibility to innovate and make product improvements quickly.*

WHAT TYPE OF SUPPORT DOES THE MANUFACTURER PROVIDE?

Another critical component in determining the appropriate device for your practice, should be the type of support you can expect to receive from the manufacturer in sales and customer service. Will they provide training on the product? Will they provide marketing materials to help inform patients? Will they refer patients? Will they be available to handle customer support issues?

At Capillus, we are committed to meeting customer requirements and enhancing customer satisfaction through continual improvement of our products, services and quality management system. Our sales representatives offer training on how to use the product, as well as how to generate more sales. We provide marketing materials to both attract and retain patients. We have plethora of tools at our fingertips, with in-house printing and video production capabilities at our corporate office.

We sell product only through our physician network, thus we refer all of our patient leads to our physicians. We rely on feedback from our physicians and their patients to improve our products and we work with them to provide the best patient care for the treatment of hair loss.

In addition, we pride ourselves in providing the best customer service in the industry. Our support team is available to troubleshoot problems and assist in an expedient manner.

Choosing the Capillus272 ensures that your patients are getting the safest, most convenient and effective laser hair treatment in the market. Our passion and dedication to excellence in manufacturing and customer support, combined with the excellent patient care of our physicians, makes the Capillus272 the right choice for your practice. We are proud of the work we do at Capillus in improving the lives of your patients, and we look forward to serving you and them for many years to come.

"Hair restoration physicians everywhere seem to agree that compliance means efficacy. The laser that will work best for the patient is the one that is proven to be effective, safe and is easy to use. The Capillus272 aims to serve that need in the most convenient way possible."

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