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FDA Clears Laser-Based Lymphedema Therapy

The Food and Drug Administration (FDA) has cleared the RianCorp LTU-904 low-level laser device as an additional weapon in the battle for better quality of life for people living with lymphedema.

After a four-year evaluation, the FDA cleared the LTU-904 for use as part of a therapy regime to treat post-mastectomy lymphedema. FDA clearance permits therapists throughout the USA to use the hand-held battery-powered device to treat a patient with lymphedema.

Lymphedema, which affects as many as 30% of post-mastectomy patients, is a chronic condition that impacts about three million people in the US. It causes a person's limb to enlarge because lymphatic fluid does not drain from the limb after the lymphatic system is compromised following breast surgery.

Since 2000, therapists in Australia have used the LTU-904 to treat patients with lymphedema.

The FDA noted that the RianCorp LTU-904 laser therapy unit has been evaluated in a placebo-controlled double blind clinical trial of post-mastectomy lymphedema patients in Australia.

Conducted under ethics committee approval by Flinders University, the study is the world's only randomized double blind study of a physical treatment for post-mastectomy lymphedema. The Flinders research team is internationally recognized in the area of lymphology and lymphedema treatment.

More than half the patients receiving LTU-904-based therapy experienced a reduction in ECF

The trial showed that 52% of patients experienced a clinically significant decrease in Extra Cellular Fluid (ECF) after six weeks of laser treatment. In contrast, only 19% of placebo patients experienced the same result. The trial's results were published in the highly-regarded peer-reviewed journal "Cancer".

The Flinders study enrolled 64 post-mastectomy patients with at least 200 ml difference between their arms. A summary of the clinical trial results is available at http://www.riancorp.com/.

The LTU-904 Laser Therapy Unit is a non-thermal device that delivers a controlled series of 200 ns bursts of pulses of 904nm laser beam. The near-infrared beam is invisible to the human eye. The FDA noted that investigators observed no adverse effects from the laser treatments and the study demonstrated the LTU-904 functioned as intended in all treatments of post-mastectomy lymphedema.

RianCorp is officially launching the LTU-904 in the USA at the 7th National Lymphedema Network International Conference, running in Nashville, Tennessee, from November 1-5.

Director of the Lymphoedema Assessment Clinic at Flinders University, Professor Neil Piller, who supervised the study, said the LTU-904 provided therapists with a powerful tool for reducing the impact of lymphedema on the lives of their patients. "The LTU-904 laser is a very significant, clinically-proven treatment option for lymphedema patients, the first new one in many years," he said.

"Current lymphedema treatments can be time-consuming, are continuous and often very expensive: They typically require patients to develop rigorous maintenance programs that are life-changing.

"The LTU-904 significantly benefits from 20-30% of treated lymphedema patients in a treatment that takes less time, requires fewer consultations and has a lower overall cost. It provides therapists with a valuable new treatment option for patients with lymphedema."

RianCorp is a privately-owned company established since 1998. The company has sold the LTU-904 in Australia, Japan, the UK and other countries. More information is available at www.riancorp.com.

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