

SoftWave Tissue Regeneration Technologies Announces Plan for Cellulite Trial

SoftWave Tissue Regeneration Technologies, a disruptive bio-medical device company, announces its plan to embark on a 60-patient study for the treatment of cellulite. SoftWave TRT has been issued a patent for the use of shockwaves to treat cellulite and numerous other aesthetic conditions. The lead investigator will be Dr. John Mullins, a Plastic Surgeon and Chief of Surgery at Piedmont Hospital in Atlanta. The study will evaluate the safety and efficacy of SoftWave's DermoGold device for the temporary improvement in the appearance of cellulite

ATLANTA, August 3, 2020 (NewsWire.com) - The study will evaluate the safety and efficacy of SoftWave's DermoGold device for the temporary improvement in the appearance of cellulite. Women between the ages of 18-50, having at least one dimple with a depth of 5mm, a Cellulite Severity Score of greater than 4 and Body Mass Index (BMI) of less than 30 will be some of the inclusion criteria.



Cellulite is different from generalized obesity in that it is a localized alteration in the contour of the skin that has been reported in over 90% of post-pubertal females and affects women of all races and ethnicities. Weight gain can make cellulite more noticeable, but cellulite may be present even in thinner subjects. Clinically, cellulite presents on the buttocks, thighs, lower abdomen and arms. The presence of cellulite is associated with changes in dermal thickness and in fat cells and connective tissue below the skin. The protrusions of the subcutaneous fat creates dimpling characteristics in the skin.

Unfocused Extracorporeal Shock Wave Therapy (uESWT) or "Softwaves" have been used for a variety of clinical conditions. Internationally, uESWT has been used since 2005 in the treatment of cellulite. A recent meta-analysis study by Dr. Knobloch and Dr. Kraemer evaluated eleven clinical trials and found uESWT was able to improve the degree of cellulite both in terms of appearance as well as in terms of ultrasound improvement of the subcutaneous fat. These studies

reported very few side effects.

Unfocused Extracorporeal Shock Wave Therapy (uESWT) guarantees both a physical and biological response and the mechanism of action is believed to be the disruption of fat components and septae to reduce cellulite. Another physical response is the reduction of lymphedema from the uESWT application. Recently it has been proposed that the influence of uESWT activating pathways is in adipose derived stem cells (ADSM). Clinically diseased skin appears to normalize following uESWT such as in progressive systemic sclerosis with upregulation of endothelial progenitor cells and circulating endothelial cells.

SoftWave Tissue Regeneration Technologies plans to begin this trial in 2020 and will be filing for a 510K clearance for the treatment of cellulite in the first quarter of 2021. This procedure lasts around 20 minutes, is non-invasive and virtually pain free and will compete with other all invasive and non-invasive surgical procedures that require anesthesia and are more costly and have potential side effects. It is estimated that women spend over \$1 billion dollars for the treatment of cellulite and SoftWave TRT believes it can be a significant player in this market after regulatory clearance.

About SoftWave Tissue Regeneration Technologies

SoftWave TRT is a bio-medical device company that has proprietary patented technology using unfocused acoustic waves to treat a variety of conditions.

The OrthoGold was first cleared in 2018 for the activation of connective tissue and registered for pain reduction and increase of blood flow. Our second clearance in 2019 was for the DermaGold for the treatment of Diabetic Foot Ulcers. SoftWave TRT has over thirty patents for a variety of indications including stem cell activation, cellulite reduction, and wound healing. SoftWave TRT plans to pursue FDA clearance for all ESWT therapies targeted by other publicly traded shockwave companies including Sanuwave (SNWV), Soliton (SOLY) and Shockwave Medical (SWAV). SoftWave believes our patented "softwaves" have superior benefits than traditional ESWT and we are conducting multiple clinical trials to demonstrate the effectiveness over current available therapies.

Contact us: info@trtlc.com or call us at (888) 862-6162x1

Source: Dr. John Mullins MD

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About Tissue Regeneration Technologies

Specializing in sales of medical devices using our patented acoustic wave technology to profoundly accelerate healing and recoveries for the human body.

<https://trtlc.com>

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