

DERMATOLOGY HIFU PRODUCT RELEASE

TOOsonix CE marks and releases new medical ultrasonic device for color-independent tattoo removal, solar lentigines, spider veins, angiomas, telangiectasia and other aesthetic conditions.

Hoersholm, Denmark, June 29th 2020 - TOOsonix A/S, a pioneer in HIFU focused ultrasound technology for dermatology, today announce that it has released its System ONE-M as a CE-marked medical device for aesthetic treatments.

The release coincides with the publication of two clinical papers in the peer-reviewed scientific journal, Skin Research and Technology (John Wiley and Sons, Inc.), describing very positive results from the first clinical treatments performed at the Bispebjerg University Hospital, Copenhagen, Denmark by the renowned Professor Jørgen Serup, MD.

The system delivers accurate thermal focal points to a chosen layer of the human skin, and directly in the lesion chosen for treatment. Applied to the outer skin the method is ablative. The system can however also reach lesions down to the dermal interface to the fat and abnormal vessels in the outer subcutis, without disturbing the out-of-focus outer skin. Thus, no wound and no scar!

"The CE marking of our first medical device is pioneering the field of HIFU used for the human skin. It is the first important step in TOOsonix' vision to make new and advanced HIFU systems available for dermatological use all over the globe. The new system is ready for a range of new applications", states Torsten Bove and Tomasz Zawada, co-founders of TOOsonix. "We initially intend to offer this device to first-mover dermatologists within the European Union, and look forward to the resulting physician feedback and market data that can guide our addition of more medical indications in the future".

Professor Jørgen Serup MD, first author of the two publications introducing the system^[1,2], comments: "High frequency HIFU has a significant potential for future use in dermatological clinics, particularly in the laser/IPL clinics, as a new and specialized member of the family of advanced devices. Tattoo removal has been studied in detail. In our experimental work we have furthermore, demonstrated that the device used for Actinic Keratosis has important advantages over photodynamic therapy (PDT), practically, resource-wise, and with respect to efficacy. Noteworthy is the reduced pain-level during treatment. HIFU can be applied to multiple sites of the body in one short session and, obviously, has the potential to replace PDT in the future. Experimental use indicates the device can be used for dedicated ablative treatment of skin cancers, particularly basal cell carcinoma, and for a range of different premalignant conditions as well as a multitude of benign skin tumors. The method is an entirely new treatment modality in dermatology, with a large potential".

For picture documentation from the studies please visit: <https://www.toosonix.com/before-and-after>.

ABOUT TOOSONIX SYSTEM ONE-M

System ONE-M is a focused ultrasound device operating at 20 MHz, which creates thermal lesion points in the upper dermis and epidermis of the human skin. Within the focal point, the temperature rapidly increases to 50–60 °C, which introduces acute cell necrosis. The body's own immune system may thereby become activated to remove and replace affected cells with new and healthy cells. The system provides an innovative and easy-to-use treatment modality that enables physicians and other qualified practitioners to offer safe and effective aesthetic treatments of their patients. Medical indications, such as Actinic Keratosis and Basal Cell Carcinoma, are already demonstrated to be highly effective, and will be added to the indicated use as soon as on-going regulatory activities are completed.

ABOUT TOOSONIX A/S

TOOsonix is a Danish company pioneering the ultrasound and dermatology field with its unique high-frequency focused ultrasound devices. The company was founded in 2017 on the foundations of more than 35 years' experience in ultrasonic technology and devices. The company has financial backing from one of Denmark's most successful private investor companies.

REFERENCES (available free of charge by open access)

- [1] Serup J, Bove T, Zawada T, Jessen A, Poli M. High-frequency (20 MHz) high-intensity focused ultrasound: New ablative method for color-independent tattoo removal in 1-3 sessions. An open-label exploratory study. *Skin Res Technol.* 2020;00:1–12.
<https://doi.org/10.1111/srt.12885>
- [2] Serup J, Bove T, Zawada T, Jessen A, Poli M. High-frequency (20 MHz) high-intensity focused ultrasound: New Treatment of actinic keratosis, basal cell carcinoma, and Kaposi sarcoma. An open-label exploratory study. *Skin Res Technol.* 2020;00:1–8.
<https://doi.org/10.1111/srt.12883>

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TOOsonix A/S, Denmark

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