
Hologic Receives CE Mark to Market SculpSure® for Non-Invasive Body Contouring of the Submental Area



Patients in Clinical Studies Report 100% Satisfaction

Hologic, Inc. has announced that it has received an additional European Medical Device Directive (MDD) certification for SculpSure®, a state-of-the-art body contouring laser treatment. The device is now certified to treat a double chin (also known as the submental area), marking the product's sixth certified body treatment area. SculpSure® is also certified to treat the abdomen, love handles (flanks), back, and inner and outer thighs.

The certification allows Hologic to place the CE Mark on SculpSure® double chin (submental) treatments for use in the European Union (EU) and its member states. The double chin (submental) treatment requires practitioners to purchase a simple laser attachment, which will allow the treatment applicators to fit seamlessly onto the area. Hologic's Cynosure sales force will begin distribution immediately to interested practitioners.

"Most patients in the 57-person submental clinical trial received two brief treatments six weeks apart," said Dr. Lawrence Bass, board certified plastic surgeon and a principal investigator in the SculpSure clinical trials. "The short treatment time, 100% satisfaction rate, and dramatic contour reductions typically seen in the study patients give SculpSure the edge as the treatment of choice for the submental area."

SculpSure® is an advanced, non-invasive body contouring treatment that helps patients achieve a natural-looking, slimmer appearance. The fully customizable treatment uses a laser to raise the temperature of body fat to precisely disrupt and destroy fat cells under the skin. The fat cells are then naturally eliminated over time and do not return. Each treatment lasts approximately 25 minutes and requires no surgery or downtime.

"The receipt of the CE Mark to treat double chin is an important growth milestone for SculpSure®," said Kevin Thornal, Divisional President of Cynosure at Hologic. "The laser's proven effectiveness rate coupled with the fact that SculpSure® is certified to treat patients with a wider BMI range than our competition in the submental area will provide healthcare professionals with a distinct treatment advantage that can drive demand and widen their patient communities."

To learn more about SculpSure® or visit SculpSure.com.

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