

Investor Relations | Hologic

Hologic Receives FDA 510(k) Clearance to Market SculpSure® for Non-Invasive Body Contouring (Lipolysis) of the Submental Area (Under the Chin)

Patients in Clinical Studies Report 100% Satisfaction Rate



MARLBOROUGH, Mass., Sept. 27, 2017 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that the U.S. Food and Drug Administration (FDA) has granted an expanded FDA 510(k) clearance for Cynosure's non-invasive body contouring product, [SculpSure®](#). The state-of-the-art body contouring laser treatment is now cleared to treat a double chin (also known as the submental area), marking the product's sixth cleared body treatment area. SculpSure® is also cleared to treat the abdomen, love handles (flanks), back, and inner and outer thighs.

"Most patients in the 57-person 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.

"We are encouraged that our chin treatment was proven effective on patients with a body mass index (BMI) up to 43, while our competition in the non-invasive arena is only FDA-cleared to treat patients with a BMI up to 30," said Kevin Thornal, Divisional President of Cynosure at Hologic. "We are excited to provide our customers with a competitive advantage that can further widen their patient communities."

To learn more about SculpSure, please visit www.SculpSure.com.

About Hologic, Inc.

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit www.hologic.com.

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Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient, as the actual effect of the use of the products can only be determined on a case-by-case basis. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such data or statements are based.

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