



Project Name: Ulthera® DeepSee®
Application: Non-invasive facial rejuvenation
Customer: Ulthera® Inc.
Website: www.ultherapy.com

Ultherapy
SEE THE BEAUTY OF SOUND

THE ONLY NON-INVASIVE FDA APPROVED PROCEDURE TO LIFT SKIN ON THE NECK, CHIN, AND BROW

BACKGROUND AND PROJECT CHALLENGE

Ultherapy is a non-surgical, non-invasive procedure for the face that uses high density, focused, ultrasound and the body's own natural healing process to lift, tone, and tighten loose skin. The system is comprised of a main Control Unit tethered to a reusable Handpiece which contains electronics and mechanical components to interface with a disposable, patient contacting Transducer.

PADT's challenge was to redesign the Ulthera® Handpiece to resolve Transducer engagement and reliability issues, eliminate the need for labor intensive hand gluing operations, and enhance the operator interface experience through improved ergonomics and pushbutton modifications. The redesigned handpiece was successfully launched into production in Spring, 2012.

PROCESS AND SOLUTION

The existing Handpiece was functional, yet difficult and expensive to manufacture and service. The system also suffered from transducer-handpiece engagement issues that were complicated by component interface and tolerancing issues. PADT approached the redesign project using a multi-company, multi-disciplined team while working within our flexible, customer-specific, FDA compliant design control process.

Step one was a collaborative effort between PADT Engineers, and Ulthera® Engineering, Marketing, CM, and Clinical professionals to identify the existing manufacturing, ergonomic, and design challenges. The collaborative output was a well defined set of user needs and design



From 2010 - 2012, PADT worked with Ulthera® to develop a new Handpiece

DISCIPLINES EMPLOYED

Mechanical Engineering
Industrial Engineering
Electrical Engineering
Verification and Validation Testing

PADT

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requirements.

We kicked off the project by attacking the performance challenges. A root cause analysis was used to identify all variables affecting the Transducer/Handpiece engagement difficulties. Three (3) designs were chosen for prototyping following a review of multiple design alternatives. A simple, robust, cantilever mechanism was chosen for the main engagement feature as it could be readily incorporated into an injection molded component while simplifying the operator interface. The scope of the project was expanded to address the mating components that were either directly or indirectly related to the handpiece improvements and transducer engagement.

The Ergonomic improvements were required to reduce operator fatigue and improve the overall aesthetics and functionality of the Handpiece. Computer and functional models were developed for review and analysis. Rapid prototyping of the handpiece shells allowed for further visual and tactile feedback during design iterations. The Human Factors considerations provided insight into the design such that the weight distribution changed to give the perception that the handpiece was lighter when no tangible weight loss occurred.

The major design and development activities included:

- Modified multiple Handpiece internal components to improve all aspects of transducer/handpiece functionality and reliability issues as identified during the root cause analysis.
- Developed a custom silicone membrane keypad assembly to significantly decrease operator fatigue, clarify the operational state, and enhance tactile feel and overall aesthetics.
- New injection molded components to incorporate the ergonomic improvements, increase robustness, simplify transducer loading, and improve manufacturability and serviceability.
- Incorporation of snap fit features into the outer shell to eliminate costly assembly processes and improve serviceability.
- Coordination with new and existing component manufactures, injection molders, material suppliers, and Ulthera's Contract Manufacturer (CM) to ensure a successful product launch.
- Evaluation of functional prototypes utilizing PADT's rapid prototyping technologies
- Verification and Clinical Validation testing
- Risk Analysis
- Successful design transfer to CM with manufacturing documentation

TESTIMONIAL

"PADT has provided a number of valuable services for Ulthera® ranging from design work and ergonomic improvements, to manufacturability and V&V testing. Over the past 18 months, PADT worked closely with our engineering staff to ensure the successful launch of our redesigned Deep See® Handpiece. Ulthera's successful collaboration with PADT allowed us to focus our internal resources on our core competencies while leveraging the PADT skill sets. Ulthera® also benefited from PADT's adaptable, customer-specific, Design Control process to minimize the QC documentation requirements on the Ulthera® staff"

- Michael Peterson
Vice President, R&D
Ulthera®, Inc

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