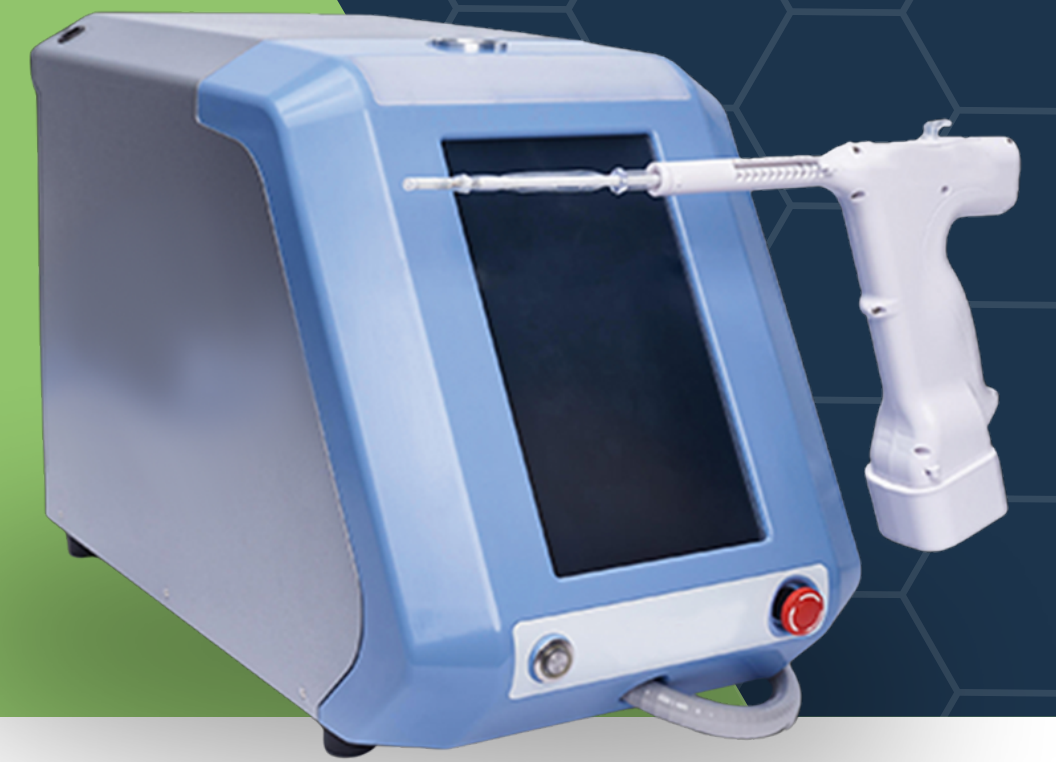


RF Ablation Device



The Device: Vapor Ablation System

Project Scope: Redesign a clinical system, providing design inputs and therapy qualification to commercial use product, support FDA submission and set up manufacturing for commercial launch.

CHALLENGES

Integration of multiple subsystems

Device calibration + system verification

Management of Risk controls

ENGINEERING SOLUTIONS

Integration of RF power supply, 8' conduit, fiber optics, multi-channel pneumatic pump with pressure sensors and syringe pump

Developed automated calibration routine that allowed an operator to press go and test test system would proceed with calibration

Integrated hardware and software safety mitigations in the Vapor Ablation System

Results:



Streamlined UI

Developed single-board computer system (SBC) which controlled touch screen graphical user interface (GUI).



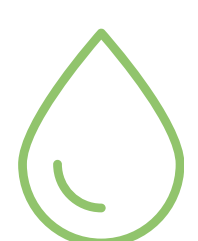
Mini-aturization

Replacement of large boiler style vapor generator
Miniaturization of components to make size smaller for client.



Cost Reduction

Cost reduction through driving strategic manufacturing of subassemblies while utilizing a global network of supply.



Ingress Protection

Water Ingress Protection while maintaining serviceability.

Project Wins:

Production and supply and management from 5 units/month to 30/month by month 6 of production launch. FDA approval accelerated 2 months ahead of plan, with no findings from FDA audit post-launch.

End point:

We now manufacture their commercially available product.