



Innovative Manufacturing for a Life-Changing Medical Device: The PoNSTM Partnership

APRIOS CUSTOM MFG AND HELIUS MEDICAL TECHNOLOGIES

Introduction

In an era of unprecedented demand for innovative medical solutions, Aprios Custom Manufacturing partnered with Helius Medical Technologies, Inc. to develop the Portable Neuromodulation Simulator (PoNSTM). This groundbreaking nonsurgical device delivers electrical stimulation to the surface of the tongue, addressing balance and gait deficits for patients with multiple sclerosis (MS) and other conditions. This case study explores the journey of this collaboration, highlighting the challenges faced and the solutions implemented to ensure success.

Project Background

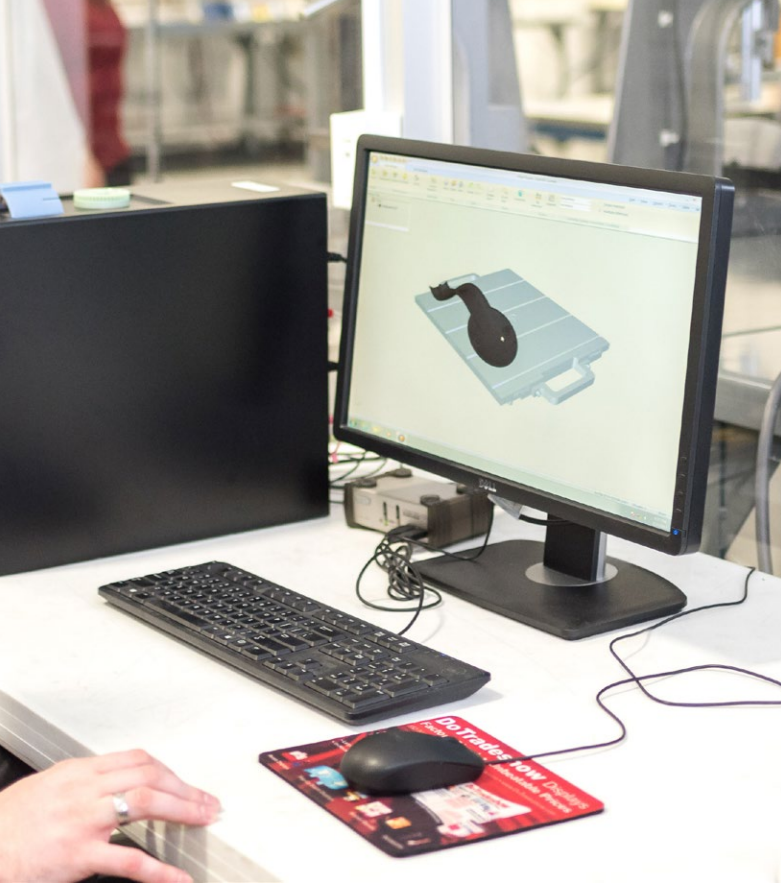
The PoNSTM device is a transformative medical innovation authorized for use in the United States, Canada, and Australia. In the U.S., it serves as a short-term treatment for gait deficits due to mild to moderate MS symptoms, prescribed alongside supervised therapeutic exercise.

Nearly 2.3 million people worldwide are living with multiple sclerosis (MS), a potentially disabling disease that often affects movement and can lead to mobility issues. In Canada and Australia, PoNS is indicated for balance deficits associated with mild to moderate traumatic brain injury and must be used with physical therapy.

The device features a complex design with close-tolerance plastic parts, necessitating sophisticated manufacturing techniques.

“Some of the components are so intricate that we can’t take the work anywhere else. I am confident in Aprios’ ability to work with us for continuous improvement and to meet growing production demand.

Gerry Huber, director, manufacturing management at Helios



Supplier Selection

Keytronic, the contract manufacturer for the PoNSTM device, reviewed potential plastic-injection molding partners and selected Aprios Custom Manufacturing for its proximity and proven ability to produce high-quality components. This choice was driven by the need for collaboration and efficient logistics to ensure a seamless manufacturing process.

Challenges

1 COMPLEX DESIGN REQUIREMENTS The intricate nature of the mouthpiece and other components required advanced manufacturing techniques and close attention to tolerances.

2 COLLABORATION FOR MANUFACTURABILITY Achieving manufacturability of the mouthpiece was particularly challenging, necessitating ongoing adjustments to dimensions and designs.

3 QUALITY ASSURANCE Maintaining high standards of quality while scaling production to meet increasing demand posed a significant challenge for both Aprios and Keytronic.

Solutions

- 1 COLLABORATIVE DESIGN ADJUSTMENTS** Aprios worked closely with Keytronic and the design house to modify designs and improve manufacturability, ensuring that the components met the necessary specifications.
- 2 CONTINUOUS IMPROVEMENT INITIATIVES** Both companies focused on reducing scrap rates and enhancing the overall production process, fostering a culture of continuous improvement.
- 3 ADVANCED MANUFACTURING TECHNIQUES** Aprios utilized its expertise in complex overmolding to create components that met both functional and aesthetic requirements, optimizing the production of the PoNSTM device.

Manufacturing Processes

- MOUTHPIECE MANUFACTURING** The mouthpiece features gold-plated electrodes and requires intricate design and precision engineering to ensure effective functionality.
- ADVANCED OVERMOLDING** One of the components underwent a double overmolding process, demonstrating Aprios' capability to handle complex manufacturing challenges while ensuring quality and durability.
- INTEGRATION AND ASSEMBLY** After manufacturing, components were sent to Keytronic for final assembly, where electronic elements were integrated, completing the PoNSTM device.

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In addition to improving the manufacturability of the parts, Aprios has made modifications to reduce scrap. PoNS is such a life-changing product, that everyone on the team wants to see it succeed and benefit people throughout the world.

Bart Bills, program manager/
planner at Keytronic

Results



SUCCESSFUL PRODUCTION

The manufacturing challenges were effectively addressed, allowing for the successful production of PoNSTM devices that meet regulatory standards and customer expectations.



POSITIVE IMPACT ON PATIENTS

The PoNSTM device has the potential to transform the lives of individuals with balance and gait deficits, providing an innovative treatment option that enhances their quality of life.



Future Outlook

As demand for the PoNSTM device continues to grow, Aprios is committed to scaling production capabilities while maintaining high standards of quality. Both companies are poised to explore further innovations in medical device manufacturing, reinforcing their partnership and commitment to improving patient outcomes.

Conclusion

The partnership between Aprios Custom Manufacturing and Helius Medical Technologies exemplifies the power of collaboration in overcoming manufacturing challenges to deliver life-changing medical devices. Through shared goals, innovative solutions, and a commitment to quality, this partnership not only addresses current healthcare needs but also sets the stage for future advancements in the field.

FOR MORE INFO PLEASE CONTACT

✉ sales@aprios.com

☎ 1.763.424.2525