



CASE STUDY

From Concept to Clearance: How Goddard & Aurie Created a Reusable Catheter System

Introduction

Thousands of individuals need to use single-use intermittent catheters every day. Current intermittent catheter products make mobility and travel inaccessible to users and are often cost-prohibitive. Additionally, standard intermittent catheter users have an increased risk of complicated urinary tract infections (UTI), with nearly 50% of them experiencing some type of infection annually¹. There are existing no-touch catheters that reduce infections by 45%. These catheters cost \$19,000+ a year, versus \$5,000 for the standard catheter that 70% of catheter users get coverage for, creating a gap between affordable and safe catheter options². Ten years ago, Souvik Paul, Chief Executive Officer and founder of Aurie, then a Master of Fine Arts student in industrial design, decided to solve that problem. “The idea was to make no-touch catheters safely reusable so that we could lower the price per use, so more people could get access to that technology,” said Paul. That’s where Aurie, a reusable catheter and reprocessor cleansing system, began. Mr. Paul brought on Marjorie Nelson as co-founder and Chief Operating Officer to turn the concept into a reality. Nelson, in turn, brought on Goddard Product Development as their MedTech product development consultancy.



Products

Reusable Catheter: A no-touch flexible catheter designed for multiple uses, intended to safely and efficiently empty the bladder while minimizing the risk of infection.

Reprocessor: A portable, compact, rechargeable device that automates the cleaning, disinfecting, and lubricating of reusable intermittent catheters.

1 Van Doorn, Tess, et al. “Single use versus reusable catheters in intermittent catheterisation for treatment of urinary retention: A protocol for a multicentre, prospective, randomised controlled, non-inferiority trial (compare).” *BMJ Open*, vol. 12, no. 4, Apr. 2022, <https://doi.org/10.1136/bmjopen-2021-056649>.

2 “DME24-C.” CMS.Gov, www.cms.gov/medicare/payment/fee-schedules/dmepos/dmeposfee-schedule/dme24-c. Accessed 27 Aug. 2024.

“We [needed] to bring in a lot of different disciplines from electrical engineering to mechanical engineering to software to industrial design to bear on the entire product suite...Goddard was really well equipped with the capabilities to supplement our own resources on all those fronts.”

– Souvik Paul, CEO & Founder

The Product Development Process

Aurie approached Goddard with a proof-of-concept model for a reusable catheter system that included a soft introducer tip, an insertion aid, and a no-touch sheath. They tasked Goddard with redesigning the product for manufacturability along with making improvements for use driven by user feedback from previous formative studies. The client also wanted Goddard to support the design control lifecycle from redesign through eventual FDA submission.

Goddard assisted with material research, determining durometer and material thickness, and provided continuous improvements through prototyping and testing, supporting enhanced mold designs.

The successful collaboration between Goddard and Aurie on the reusable catheter led Aurie to expand the scope of work to include the reprocessor, bringing the electrical and firmware engineering teams onto the project.

Electrical engineers focused on the system's rechargeability and power supply, board design, and pressure and temperature sensors. Goddard's industrial design team worked on surface modeling, aesthetic design, and the overall footprint of the enclosure.

The mechanical engineering team focused on the piping and instrumentation diagram, developing the architecture for the internal cleaning and disinfection system. They also worked on the enclosure design, ensuring proper placement of internal components. Goddard and Aurie collaborated to design water-tight connections where the systems interfaced with the catheter.

Software and firmware engineers focused on the sequencing of the cleaning cycle, managing valve timing and fluid circulation, as well as time-based alerts. They also developed the code for the User Interface, ensuring the functionality of the menu and buttons, which contributed to the success of the mechanical and electrical engineering teams.

“One of the high points of this experience really has been this cross-functional team that we’ve worked with – mechanical, electrical and firmware, we’ve had some great support from those groups. Though we’ve encountered challenges as we’ve had to extend our approach to the development effort and look at more and different technologies that we didn’t expect we were going to need, there’s somebody here that’s had experience with some of them.”

– Marjorie Nelson



What Did We Learn?

Developing a novel product invariably comes with challenges, and Goddard certainly faced a few while creating this system. Each challenge presented an opportunity for improvement and innovation, ultimately resulting in a superior finished product.



Supply Chain

The program encountered material lead time issues that impacted real-time design decisions. The team addressed these challenges by leading a sourcing effort to procure the most compatible materials and by purchasing an excess of certain components to mitigate future shortages and long lead times.



Structure & Materials

The mechanical engineering team encountered pressure issues with the reprocessor. The team ran finite element analyses (FEA) to see how structure and material could be added without increasing the overall size of the parts, which they managed successfully. They learned the importance of leaving room to add support when optimizing the design for fit or size, until the operating pressure is confirmed.

What's Next?

Aurie is verifying and validating the catheter and reprocessor for FDA-submission. Following FDA clearance, Aurie is already planning their next developments. “We’re ... developing other technologies [with Goddard] that could potentially sense infections before the symptoms appear, so that antibiotic stewardship and utilization can be more efficient,” said Paul. In addition to infection detection, Aurie aims to expand their software and complete more Human Factors (HF) studies with Goddard’s dedicated HF Engineering team.

Conclusion

The Aurie reusable catheter system is a product that truly evolved through design and “the partnership with Goddard really helped [Aurie] stretch their dollar and do a lot of things [they] wouldn’t have been able to do.” Aurie shared that Goddard provided access to “incredibly talented people who brought a breadth and depth of experience to the project.”

At the time of publishing, Aurie is preparing the system for validation testing. Interested in making your ideas a reality? Set up a free consultation with Goddard today.





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goddardpd.com | (978) 524-8884
hello@goddardpd.com

