Webinar:
(July 2nd, 2025) The World's Smallest Pacemaker: Design and Applications

Questions and answers from the July 2nd, 2025, webinar titled: "(July 2nd, 2025) The World's Smallest Pacemaker: Design and Applications"

This document includes questions we received and answered during the webinar, as well as those that we did not have time to address.

Q1: Do you need to modify the pacemaker when scaling up from rodents to larger models or clinical applications?

A:No modifications were needed. The device's compact size allowed us to test it across models, starting with rodents and moving up to rabbits, pigs (ex vivo and in vivo), and even human donor hearts. We also successfully targeted areas like the His bundle for selective pacing and implanted multiple pacemakers to explore coordinated, multi-site activation.

Q2: What's the envisioned future for delivering the device in clinical settings?

A: We're working toward ultrasound-guided injection of the pacemaker, eliminating the need for fluoroscopy. This approach would enable emergency implantation by EMS or in ER settings where imaging tools are limited, offering rapid cardiac support.

Q3: Is the pacemaker delivered via syringe? If so, does this cause tissue damage?

A: Yes, the device is designed for injection via a 14-gauge syringe. It's placed on or just below the epicardium. It adheres using UV- or temperature-activated conductive glues. These methods avoid damage to cardiac tissue and reduce fibrous capsule formation. For short-term use (7 to 10 days), the device dissolves before significant fibrosis can occur.

Q4: How is the pacemaker powered and how is data transmitted?

A: The device is powered via a galvanic battery and activated by a wearable module with LED light. Data is transmitted wirelessly via Bluetooth to a mobile app. The system supports closed-loop functionality, automatically adjusting pacing when heart rate drops, and allows tuning of pacing frequency and pulse width.

Q5: Can this system be integrated into typical clinical setups, or does it require specialized equipment?

A: It's designed to be adaptable to standard clinical environments. While current testing is preclinical, future iterations aim to be compatible with commonly available devices and platforms.

Q6: Is the device suitable for congenital conditions like situs inversus or pediatric applications?

A: Yes. Pediatric use is a key target. Traditional leads are not feasible in infants due to size, and re-implantation is often necessary as the child grows. The pacemaker can help in congenital defects like tetralogy of Fallot, ASD, or VSD, potentially integrating with closure plugs. We also plan to utilize minimally invasive approaches, such as subxiphoid with CardioPort, for infant delivery.

Q7: Can the device be used for both congenital and acquired conduction blocks?

A: Yes. There's no difference in application. Whether the block is congenital or acquired, such as post-MI or after TAVR procedures, the device functions effectively. We've tested it under both conditions.

Q8: How are you evaluating the resorbable properties and biological clearance of the device?

A: We use a combination of ultrasound imaging, histology, and blood work to assess biocompatibility and clearance. These tests check for inflammation, tissue response, and byproducts like zinc or molybdenum to confirm safety.

Q9: What's the timeline for clinical translation?

A: We've launched a company, Nusra Biosystems, to bring the technology to market. We're aiming for first-in-human trials in approximately 2 years, though full clinical integration may take up to 5 years. We're pursuing breakthrough device designation to streamline FDA interaction and are collaborating across institutions including Northwestern, UCLA, Mount Sinai, and European partners.