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Securisyn Medical awarded a $1.95M SBIR Fast-Track Grant to develop SolidAIRity Flex™ Pediatric and Neonatal Endotracheal securement devices for improved clinical safety and outcomes by reducing Unplanned Extubation in mechanically ventilated children

Littleton, CO – [September 20], 2021; Securisyn Medical LLC, a provider of novel breathing and smooth tube and catheter securement products dedicated to improving patient outcomes, today announced the award of a Fast-Track Small Business Innovation Research (SBIR) grant by the Eunice Kennedy National Institute of Child Health and Human Development (NICHD). The NICHD, which is part of the National Institutes of Health (NIH), awarded the collaborative grant to support Securisyn Medical's development and clinical testing of its novel neonatal and pediatric endotracheal securement devices to reduce the unintentional removal of a patient's life-sustaining breathing tube, a life-threatening complication referred to as Unplanned Extubation (UE). This grant award was made in partnership between Securisyn Medical, Minnesota HealthSolutions Corporation (MinnHealth), based in Minneapolis/St. Paul, MN), and The Children's Hospital of Los Angeles (CHLA). Nick Rydberg, MinnHealth VP of Engineering, will serve as the principal investigator (PI), joined by clinical investigators Robinder G. Khemani, MD, MSc and Narayan Iyer, MD, from CHLA.

Mechanical ventilation through an endotracheal tube is routine in the PICU and NICU environments and has contributed to improved survival and reduced morbidity. However, neonatal patients, infants, and other children of all ages have unique challenges with endotracheal tube securement and are at particularly elevated risk for unplanned extubation due to anatomic and physiologic factors. UE is common in mechanically ventilated patients in the NICU (Average = 18.2%; Range 1.0% - 80.8%) and the PICU (Average 8%; Range 0.8% - 18.5%) [1]. Unplanned extubation is potentially devastating and costly, often leading to a variety of serious, life-threatening cardiovascular and respiratory complications, increased hospital length of stay (16.5 days vs 10 days), increased attributable hospital cost per event by $36,000, and is the fourth most common adverse event in NICUs in the United States.

The reviewers from the Center for Scientific Review Special Emphasis Panel, Respiratory Sciences Committee, noted, "Securement of endotracheal tube is vital to premature babies who require months of intubation in pediatric and neonatal intensive care units. Current tube securement requires tapes, which is detrimental to the highly sensitive skin of small babies. A tape-free, better tube securement device is critically needed to ensure reliable mechanical ventilation. With their convincing commercialization plan, the investigators laid out a promising marketing potential for endotracheal tube securement devices. A main strength of the proposal is attributed to the complementary expertise of the investigators. Their extensive experiences in pediatric endotracheal intubation and mechanical ventilation, their technical competence in development and commercialization of medical devices and their

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collaboration with an excellent clinical site for product validation are highly regarded. The simple securement system using a patented novel interlocking stabilizer concept to eliminate the use of tape is a major innovation of the proposal. The plans for designing and manufacturing prototypes in the Phase I stage and advancing the prototype design to a finished product and validating the performance, safety and efficacy in a phase 2 clinical trial are logical and rigorous."

Mark Bruning, CEO of Securisyn Medical, commented, "The SBIR grant program is incredibly competitive and winning this grant is another validation of our innovative interlocking approach to improve the safety and outcomes of ventilated patients. This timely Fast Track SBIR I/II funding from the NIH is a major step forward towards final design/prototyping, manufacturing, regulatory pathway, a human clinical trial, and advancing this important addition to the SolidAIRity™ family of breathing tube securement products for the entire spectrum of patients who need them, and the highly-trained clinicians with the significant responsibility of caring for them."

Nick Rydberg, added, "MinnHealth is very focused on bringing innovative products to market and looks forward to a successful collaboration with Securisyn and CHLA in the development of these pediatric and neonatal endotracheal securement devices."

About Securisyn Medical, LLC.
Securisyn Medical, LLC (www.securisyn.com) headquartered in Littleton, Colorado, is an innovative medical technology and solutions company dedicated to enhancing ventilated patient safety and broader smooth tube and catheter securement. The company is focused on eliminating preventable deaths related to airway management and catheter migration and has selected life-threatening conditions of UE with its patented SolidAIRity® family of airway securement devices as the initial clinical application of its technology.

About Minnesota HealthSolutions Corp.
Headquartered with research and development facilities located in the downtown core of the Minneapolis/St. Paul metropolitan area, MinnHealth (www.minnhealth.com) develops, evaluates and deploys novel high-impact technologies in a wide variety of regulated health and medical markets.

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1. Silva, P.S., et al., Unplanned extubation in the neonatal ICU: a systematic review, critical appraisal, and evidence-based recommendations. Respir Care, 2013. 58(7): p. 1237-45.