



# SECURISYN MEDICAL

Inventing the  
standard of care.

## Securisyn Medical Receives FDA 510(k) Clearance for its SolidAIRity™ III Airway Stabilization System

**HIGHLANDS RANCH – October 9, 2019** – Securisyn Medical, LLC, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) to market its SolidAIRity™ III Airway Stabilization System (“SolidAIRity™”) for airway management of patients requiring oral intubation. The company, dedicated to making airway management safer, has pioneered the first, fully integrated airway stabilization system designed and patented to provide unmatched airway stability for ventilated patients.

“FDA clearance of SolidAIRity™ is a major milestone in the progress towards a long overdue solution for unplanned extubation, a significant threat to ventilated patient safety. When a patient’s life-sustaining breathing tube is accidentally pulled out of the airway, significant harm and death can occur,” said Dr. Art Kanowitz, Co-Founder, Chairman and Chief Medical Officer of Securisyn Medical. “Each year, unplanned extubation impacts more than 121,000 critically ill or injured patients, some who suffer irreversible brain damage and others who lose their life prematurely from this preventable complication. A single unplanned extubation leading to a preventable death is one too many. That is why our passion and mission at Securisyn has become zero harm and death from unplanned extubation. The invention of SolidAIRity™ is the first transformative step in our journey of honoring patients like Drew Hughes, a teenage boy whose life was cut far too short in 2013.”

Despite use of adhesive tape and other commercially available tube holders, inadequately stabilized breathing tubes are unintentionally removed in a median of 7.3% (range 0.5-35.8%) of adult mechanically ventilated ICU patients. Those patients are at higher risk of hospital acquired conditions such as, ventilator associated pneumonia or vocal cord injury leading to increased length of ICU and hospital stay or possible hospital re-admission. “Even in the most controlled health care environments, the long-standing approaches of trying to effectively grip a smooth, slippery plastic tube don’t work - and they never have. As the world’s first integrated breathing tube securement system, SolidAIRity’s™ novel, ribbed endotracheal tube and interlocking stabilizer stand up to more than 7 times greater force than the leading competition, while maintaining unrestricted air flow,” added Mark Bruning, President and Chief Executive Officer. “SolidAIRity™ provides caregivers a new treatment option thoughtfully engineered with patient safety and clinician satisfaction top of mind. In my career as a direct care provider and healthcare organization leader, I have personally seen the unfortunate consequences of unplanned extubation and believe SolidAIRity™ has real potential to revolutionize airway safety and become the new standard of care.”

Complications of unplanned extubation increase the overall cost burden in U.S. adult ICU’s by almost \$5 billion every year. “As our healthcare system looks for cost efficiencies and trends toward value-based care, we are eager to launch a disruptive technology that we are highly optimistic can reduce wasteful spending and lower the total cost of care.” Elyse Blazeovich, Securisyn Medical Co-Founder and COO/CFO, stated, “In the coming months, during a limited market release, we look forward to partnering with select quality and safety-focused healthcare organizations who recognize

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the prevalence of unplanned extubation, are enthusiastic about proactively adopting our solution-focused technology and will help us track clinical and economic impact data to support evidence-based treatment decisions for SolidAIRity™.”

## References:

1. Berkow, L. MD. Unplanned or accidental extubation in the perioperative environment. *Anesthesiology News Airway Management*, 2019. p.71-77.
2. 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.
3. Data on File at Securisyn Medical.

## About Securisyn Medical, LLC.

Securisyn Medical, LLC ([www.securisyn.com](http://www.securisyn.com)) headquartered in Highlands Ranch, Colorado, is an innovative medical technology and solutions company dedicated to enhancing ventilated patient safety, preventing unplanned extubation and its associated complications, providing peace of mind for patients, their families, and practitioners and decreasing healthcare costs through ethical, profitable, and sustainable business practices. The company is focused on collaborating with stakeholders around the world to eliminate preventable deaths related to airway management.

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