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LINEAR[®] HEALTH SCIENCES

OKLAHOMA CITY, OKLAHOMA

CONTACT

Dr. Ryan Dennis, Founder and CEO

YEAR FOUNDED

WHO'S BEHIND IT

Ryan Dennis,MD, a hospitalist and medical director of Carter Healthcare (Oklahoma City, OK), mechanical engineer Adam Waters, co-founder & CTO; Dan Clark cofounder & CMO (who has a background in industrial engineering and global business development)

UNMET CLINICAL NEED

Accidental dislodgement of IV catheters is a frequent problem that causes patients pain and racks up unnecessary hospital costs

SOLUTION

A release valve that attaches to existing IV administration sets, breaking away harmlessly and automatically sealing from both ends if it senses a sudden force on the line

FUNDING \$1.25 million

INVESTORS

i2E (Innovation to Enterprise)'s Oklahoma Angel Fund and other healthcare professionals

LINEAR HEALTH SCIENCES: THE WORRY-FREE FUTURE OF THE IV

Linear Health Sciences has recently unveiled its flagship product, the Orchid Safety Release Valve, an innovative answer to an issue that impacts the satisfaction and safety of patients and nurses alike, as well as the bottom lines of hospitals across the country.

In the years following the completion of his residency, hospitalist Ryan Dennis, MD, the founder of **Linear Health Sciences** (LHS), took note of a fairly common problem among his numerous patients; their IVs were becoming dislodged in the middle of the night. He would receive calls from nurses who were unable to reestablish access without a PICC line (Peripherally Inserted Central Catheter), which can be unavailable at those late hours, or a much more invasive central line, which would require placement by a doctor. Furthermore, even if a dislodgment occurred during the day, gaining peripheral access was par-

Dislodgement is one of the primary IV failure modes, occurring with 10-25% of all lines placed.

ticularly difficult with certain patients, and a central line would need to be implemented.

One case in particular stands out to Dennis as part of the inspiration for his solution to the problem, the *Orchid Safety Release Valve*. "I had a patient in the emergency room," he recalls, "who had a chest tube in for a pneumothorax caused by a collapsed bulla." Though she was experiencing some pain, she was doing fine that evening, so Dennis went home, only to return the next morning to a distressing report of the night before. The patient had gotten up to use the bathroom when her chest tube caught on her bed railing, pulling out the tube and surrounding sutures. Her lung recollapsed in the process. Before Dennis' arrival, she had spent hours in excruciating pain because no available personnel could reinsert the tube. As he listened to her story, Dennis was convinced that there must be an alternative with less pain and less trouble. He thought of another device that was easy to reconnect after accidental disconnection—the magnetic charger of his laptop. It only made sense to him that IVs should be just as hassle-free, ensuring the connection while minimizing the risk of damage to either side of the connection when removed. He decided then and there to develop an out-of-the-box solution for securing medical tubing with these priorities in mind.

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COLIN MILLER,

CONTRIBUTOR

Initial brainstorming yielded the idea of a break-

away valve analogous to that on a gas pump which releases the hose and stops the flow of gasoline should a car attempt to drive away with the nozzle still inserted. Dennis reached out to Adam Waters, with whom he had developed a friendship stemming from the fact that both their wives worked together as nurses. Waters had previously shown him some industrial projects he had worked on in valve tech-

nology for the oil industry, and making a natural connection, Dennis asked if Waters could design a nonmetallic, miniaturized solution for the dislodgment problem he described.

The next step was to commercialize. Dennis turned to his college fraternity brother Daniel Clark, who had been working with some major strategics in infusion disposables and seen several products brought to market, and whose business experience would round out the core team. The founders began working nights to quantify the market and get some initial interest from functional users in the form of surveys. Once they had the numbers to work with, Waters, the engineer of the group, took on the task of iterating their original design, which proved both practicable and cost-effective.

Bearing a visual resemblance to a standard needle-less connector, the Orchid Safety Release Valve is applied by nursing staff in the same fashion between the IV administration set and the IV extension set. If the line snags on something, the device breaks away and seals off on both sides, protecting the infusion (which could range from cheap saline to precious chemotherapeutic agents) from leaks and backflow. It also sends an alert signal to nursing staff once it registers the break in the connection. The responding staff need only replace the Orchid valve by screwing off the broken halves and placing a new valve in between (see Figure 1). Thus, for just two dollars, the cost of the Orchid valve, a peripheral line that might have otherwise cost \$30 in time and resources can be salvaged.

In Dennis' experience, clinicians brought up two points of concern when the Orchid was pitched. First was skepticism of existing IV dislodgment data. No definitive study exists on the subject yet, though Dennis ultimately aims to carry one out once LHS secures its place in the market, generating data via the pilots that make up the bulk of their commercial launch process. For now, he and his team have been holding focus groups, using some of the existing data to get a baseline for dislodgment rates and gathering their own from records of dislodgment specifically due to tension kept by daytime nurses at Dennis' hospital, which reflected the figures encountered in the literature. Current data shows that dislodgment is one of the primary IV failure modes, occurring with 10-25% of all lines placed. With 300,000,000 peripheral lines in the United States, those costs add up. If it's an expensive IV drug or a central line being protected, the sav-



ings increase exponentially with the use of the Orchid valve.

The second concern surrounded the integration of the Orchid into administration sets currently on the market. Moving forward, strategic partnerships with existing IV set manufacturers would eliminate the problem of Orchid valves being left on the supply shelf simply because they're a separate, individual component. "We want this to be on every line, every time," says Dennis, believing it to be "a standard-of-care-shifting" technology. He cites companies like Becton Dickinson, 3M, Baxter, B. Braun Melsungen, Hospira, and Medtronic among those with whom he has interest in exploring partnerships. Furthermore, though they began with valves for IV tubes which have lure closures on both sides, Dennis' goal is to apply the platform technology to the chest tubes that originally helped inspire the product as well as portable insulin pumps and other devices for active, ambulatory patients for whom dislodgment presents a risk.

For patients, the *Orchid* means less pain and a reduced chance of having to resort to more invasive lines. For nurses, it means exposure to fewer sharps and bodily fluids, not to mention workflow efficiencies in terms of not having to spend time placing new IVs. Perhaps the most dramatic impact of all, however, is that upon hospitals' bottom lines. Using the base case numbers of a \$30 line restart (factoring supplies and labor) and a \$2 unit cost for the device, the average 160-bed hospital would be expected to see \$240,000 in annual savings. Extrapolation over all US hospitals would translate to nearly \$1 billion in nationwide savings. Plus, according to Dr. Dennis, the device could significantly reduce potential for infiltration, phlebitis, and lineassociated infections.

The development team is currently undergoing final design, verification and validation in preparation for 510(k) FDA clearance. Because of the FDA's special framework for infusion disposables, they expect an expedited clearance process and anticipate a release date in the third quarter of 2017. At that point, Dennis hopes to establish relationships with strategics in order to sell to hospital buying committees. Initially, he says this will mean demonstrating commercial traction by following a direct sales model with pilot protocols in place to generate data to quantify and prove the savings he projects. 🚺