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## Media Backgrounder

# Orchid Safety Release Valve

The Orchid Safety Release Valve™ (SRV) is a single use, inline, tension-activated safety release valve. It is intended to address the issue of accidental IV dislodgements caused by tension-based events that affect IV tubing. In particular, it is designed to mitigate many of the downstream consequences of dislodgements.

The novel Orchid SRV is placed between the IV administration set and extension set. It activates when a force beyond the device's threshold level is exerted on the IV line. Safety release valve activation immediately ends the force's impact on the line and closes off the flow path, creating a sterile barrier between the medical tubing and open-air environment. This self-sealing feature protects both IV hub site integrity and the infusion product itself.

To restart treatment, the caregiver simply removes and disposes of the activated Orchid valve halves and replaces them with a prepackaged, sterile Orchid SRV. Thus, treatment is restored without a new needlestick or other, more invasive procedure. The device does not itself cause dislodgement and does not disrupt normal nurse workflow.

The Orchid's breakaway properties are somewhat analogous to breakaway hoses at gas stations pumps, which prevent the full hose from being pulled out of the pump when an absent-minded driver drives away without removing the nozzle from the gas tank.

## **How Was IV Dislodgement Previously Addressed?**

Healthcare providers know from experience that a substantial number of IV dislodgements will occur because the standard methods of IV securement cannot completely prevent them. The literature underlines this conclusion. No published studies have yet focused specifically on accidental dislodgement, but rates of occurrence are available in published research on related issues – e.g. IV catheter-related complications. Dislodgement rates in five published prospective randomized studies reviewed by Helm et al. in 2015 range from 3.7%-9.9%, with a mean of 6.9% and a median of 7.3%. The same authors calculated the mean in the eight prospective

observational studies they reviewed to be 17.5% and the median 9.2%.<sup>1</sup> When dislodgements take place, providers normally address them with time-consuming IV restarts – because without a device like the Orchid SRV, there is no other way to respond.

## **Why Is Orchid SRV Necessary?**

In general terms, a new category of IV technology – i.e. a Safety Release Valve – was needed because there were no other paths to preventing the downstream consequences of dislodgements. Many dislodgements occur not because a line is incorrectly placed or secured but simply because the forces exerted on the line overwhelm the current securement methods. There were no previous devices or changes in nursing practice that could address this problem or its consequences. The Orchid SRV fills that gap.

To return to the gas pump analogy, there will always be drivers who inadvertently drive away with the nozzle still in their gas tank -- but a breakaway device can prevent the worst consequences from occurring. The potential consequences of IV dislodgements include serious clinical complications -- even death in rare instances -- and substantial costs for the healthcare facility.<sup>2,3,4</sup> So there was a clear need for a cost-effective solution that also eliminated or at least minimized the clinical impact of dislodgements.

## **Advantages for Patients, Nurses and Hospitals**

### **For patients:**

- \* Fewer IV restarts including painful needlesticks
- \* Reduced potential for more invasive treatment such as central lines due to loss of peripheral IV integrity

### **For nurses:**

- \* Greater efficiency through avoiding dislodgements and unscheduled IV restarts
- \* Less exposure to sharps injuries and potentially infected blood

### **For hospitals:**

- \* Reduced potential for infiltrations, phlebitis and healthcare-acquired infections
- \* Cost savings due to more efficient use of nursing time and less need to replace entire IV setups because of accidental dislodgements
- \* Greater patient satisfaction

Linear Health Sciences is currently pursuing FDA clearance for the Orchid SRV.

## Footnotes

1. Helm RE, Klausner JD, Klemperer JD, Flint LM, Huang, E. Accepted but unacceptable: peripheral IV catheter failure. *J Infus Nurs.* 2015; 38(3):189-203.
2. Wallis MC, McGrail M, Webster J, Marsh N, John Gowardman J, Playford GE, et al. Risk factors for peripheral intravenous catheter failure: a multivariate analysis of data from a randomized controlled trial. *Infect Control Hosp Epidemiol.* 2014; 35(1):63-68. doi: 10.1086/674398.
3. Schatzlein K. Hold tight: keeping catheters secure. *Nursing.* 2003; 33(3):20-22.
4. Giuliano KK, Niemi C. The urgent need for innovation in I.V. infusion devices. *Nursing.* 2016; 46(4):66–68. doi: 10.1097/01.NURSE.0000480617.62296.d7