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DEVICE PROFILE

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Device profile of the Orchid safety release valve for the prevention of accidental catheter dislodgement

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ABSTRACT

Introduction: More than 4 out of 5 patients in acute care require intravenous catheters. Complications of catheter dislodgement and failure are commonly reported at rates of 15–69% causing interrupted treatment and greater resource consumption when catheter replacement is required.

Areas covered: This manuscript outlines unmet needs in the prevention of catheter dislodgement and how a novel safety release device (Orchid SRV™, Linear Health Sciences) might address these gaps based on available evidence.

Expert opinion: Healthcare initiatives focus on reducing complications and associated costs with the delivery of intravenous treatments. Tension-activated safety release valve devices, attached to intravenous tubing, are a new feature that adds a level of safety to intravenous catheters to reduce mechanical catheter dislodgement when a pull force of greater than 3 pounds is applied. Incorporating a tension-activated accessory into and between existing intravenous tubing and the catheter and extension set protects the catheter from dislodgement. Flow continues until excessive pull force separates and closes the flow pathway in both directions, while the SRV provides a quick replacement to reestablish flow. The safety release valve is used to prevent accidental catheter dislodgement, limit tubing contamination, and avoid more serious complications while maintaining a functional catheter.

PLAIN LANGUAGE SUMMARY

It is common for intravenous treatment to be disrupted due to accidental dislodgement of the catheter. Once this happens, the catheter must be replaced. This dislodgement may cause patient discomfort, loss of intravenous access to treatment, increase the chance of catheter failure due to blockage, and increase the risk of life-threatening infection. A new tension release device, the Orchid SRV, is designed to increase patient safety with a release valve, activated with any pulling force on the connected tubing, to prevent dislodgement and complications associated with catheter failure.

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Accidental dislodgement; catheter; complications; peripheral intravenous catheter; safety

1. Introduction

Treatment delivered through peripheral intravenous (PIV) catheters is the mainstay of medical practices in acute care. An estimated 80% or more of patients admitted into acute care require some form of intravenous (IV) access. The primary goals of IV device care are successful IV insertion and maintenance and the prevention of catheter-related complications. When IV devices fail, become dislodged, or develop complications, medical treatment is hampered, and patients require more invasive procedures, such as re-insertion of the IV. The failure rate associated with PIV catheters is well documented at or above 46%, with dislodgement estimated at 15–69% [1–4]. Complications attributed to catheter dislodgement include infiltration, venous phlebitis, catheter occlusion, and failure. Preventing complications, dislodgement, and catheter failure is, therefore, essential to the completion of intravenous therapy and medical treatment.

Infusion therapy for patients is predominately performed through the connection of a fluid medication bag and administration tubing, all attached to a patient's indwelling IV catheter. Continuous infusions of medications or solutions require the patient to maintain a constant connection to the IV. The normal patient activity of bed transfers, transportation to different departments, movements in bed, frequent trips to the bathroom, and even patient confusion can all result in excessive pulling on IV tubing. As the tubing becomes stretched, the tension is transferred to the catheter and dressing with subsequent loosening of securement and accidental removal of the IV catheter. Forceful removal of the catheter and dressing can cause injury to the patient, skin damage, and loss of venous access. Prevention of accidental catheter dislodgement through the insertion of a safety releasing valve can relieve the tension on the tubing and catheter to protect the patient and facilitate uninterrupted treatment. The Infusion Nurses Society (INS) Standards recommend using catheter protection devices for specific patient populations, including pediatric, elderly, and those with cognitive dysfunction at risk for the catheter being accidentally dislodged or removed [5]. A responsibility to patients exists to provide safety devices, when available, to prevent these types of complications.

IV catheters used for the infusion of fluids and medications include peripheral short or long catheters (PIV), midline

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Article highlights

- Accidental dislodgement of intravenous catheters is a common complication, often requiring catheter replacement and resulting in other adverse patient outcomes.
- Accidental dislodgement is associated with the inadvertent force of greater than three pounds of force applied to the intravenous catheter and tubing.
- Orchid Safety Release Valve (Orchid SRV™) is a sterile medical device designed to provide force-activated tension separation between peripheral intravenous catheters and administration tubing to minimize catheter dislodgement, thereby reducing associated patient complications.
- The design of the SRV allows separation with a safe seal of both connections, eliminating the loss of intravenous solutions and causing the electronic infusion pump to alarm while alerting the clinical staff to replace the SRV device.
- Safety release valves perform an important function in protecting patients from contamination and other complications that can result from accidental dislodgement of the catheter.

catheters, peripherally inserted central catheters (PICC), non-tunneled and tunneled central venous catheters, femoral, apheresis, dialysis catheters, and arterial catheters that cover all patient populations for the delivery of infusion therapy [5–11]. Each of these types of IV devices may result in failure due to dislodgement with the maintenance of IV access seriously affected. The risk to the patient with catheter dislodgement is increased with different types of IV catheters, larger catheters, central positioning, and vein access points that reflect a greater life-threatening danger of air emboli or hemorrhage. According to an ECRI Polyurethane Medical Device Material Safety Report published in 2021, peripheral arterial catheters, PICCs, and central venous catheters experience complete dislodgement as a safety issue [12].

Catheter dislodgement is considered a common clinical occurrence, with approximately 5 million – or one in four – dislodged catheters reported in the U.S.A each year. Incidence of IV catheter dislodgement in adult and pediatric patients has been estimated at up to 69% [4]. It is widely believed that this catheter dislodgement is widely under-reported and that many more catheters are subject to failure and negative outcomes. A recent survey of 1426 respondents indicated clinicians routinely observe accidental IV catheter dislodgement in their patients, with 68% of clinicians reporting dislodgement often, daily, or multiple times daily. Accidental dislodgement was most frequently observed in PIV catheters, according to 96.5% of respondents [13].

A dislodged catheter is not generally easy to replace. Successful venous catheter insertion is difficult and time-consuming, as multiple insertion attempts are often necessary. Lack of treatment or delay of medication infusion due to loss of intravenous access may worsen the patient symptoms and even result in patient death. Thus, there is a critical need to prevent catheter dislodgement at the outset to ensure prompt intravenous delivery of medication [14,15]. In a Cochrane Review of complications in 2015 by Ullman and associates, the authors stated, 'Dressings and securement products are used to prevent infectious and mechanical complications; however, current complication rates suggest customary practices are inadequate.' Published studies prove that securement alone, in any form, does not prevent accidental dislodgement of IV catheters in any patient population [16].

Safety precautions are especially indicated for the more vulnerable populations of pediatric and geriatric patients who are more greatly affected by the cessation of treatment or with complications associated with accidental dislodgement. There is value and risk reduction in protecting these very young and older age groups from complications. In these populations, tubing and catheter disruptions are common due to high activity levels in children or confusion in the elderly. In addition, both groups have difficult venous access issues, small and fragile veins, and may suffer from depletion of available veins when IV infusions are required. Thus, preserving available veins, and safeguarding the catheter and patient during infusions, are both of high importance for patients that warrant the need for added safety devices.

A special group of technologies, known as set protection devices, or force-activated separation devices (FASD) has been created to address the prevention of catheter dislodgement [3]. Using a safety release valve in line with the existing tubing, the technology is designed to allow for disconnection of the tubing when undue pressure or pull is placed on it. By preserving the entire IV tubing and catheter insertion site, this technology acts as a safeguard against patient or staff accidental catheter dislodgement and has proven to reduce mechanical complications supporting these devices as time-saving alternatives that promote safety [3,17,18]. This review outlines the function, stress testing, and clinical efficacy of a safety release device (Orchid SRV™, Linear Health Sciences) designed to reduce and prevent accidental intravenous catheter dislodgement.

2. Introduction to the safety device

The Orchid Safety Release Valve (Orchid SRV™ or SRV) is a sterile, single-patient-use connector for needle-free access. It is placed between the existing IV extension set and general IV tubing connection intended for use in the delivery of fluid to and from a PIV catheter. The safety release device is installed within the tubing of IV or intra-arterial administration sets, for continuous or intermittent infusions. When activated by tension on the IV tubing, the valve separates, creating a sterile seal for both sides of the fluid pathway, thereby preserving the IV catheter for continued use.

The device design is a two-piece bonded structure that allows the separation of the device into two parts when the predetermined disconnect tension force reaches or exceeds 3.25 pounds of force (lbf) (Figure 1). Given adequate force, the device interlocking arms, in the center of the device, separate creating the two sealed halves that protect both connection points of the IV administration tubing and the IV catheter. The device separation of the safety valve into the two halves creates an automatic sterile seal for the fluid pathway. The seal is established to maintain the aseptic integrity of the indwelling catheter and the fluid pathway for the IV administration tubing, stopping the infusion, and protecting the catheter. After separation, the two parts of the SRV remain

Figure 1. Schematic diagram of the Orchid SRV™ device. Used with permission from Linear Health Sciences.

Figure 2. The Orchid SRV™ placed between an IV extension set and general IV tubing connection. Used with permission from Linear Health Sciences.

attached to the tubing end and the needleless connector catheter end. The infusion seal and fluid flow stoppage cause the electronic infusion pump to alarm occlusion, alerting the clinician to check and replace the SRV device. The clinician then reconnects a new SRV onto IV tubing and catheter access by simply removing the separated halves and replacing them with the new, prepackaged, sterile valve using an aseptic technique.

3. Device function and clinical profile

The Orchid SRV functions to protect the patient and IV catheter from complications associated with accidental dislodgement. The patented SRV (US Patent No. 9,861,805 B2) is intended for U.S.A prescriptive use with patients 18 years or older who require a peripheral intravenous device. Intended for the delivery of fluids or medications into a PIV, the device is placed between the standard IV administration tubing and the existing IV catheter extension set Luer connection (Figure 2). When excessive force acts on the IV tubing, the Orchid SRV separates and closes the flow path in both directions. This activation of the safety release valve makes replacement and the return to the treatment infusion flow, fast, simple, and clean, while improving both the patient and clinician experience. Replacement following the separation of the valve is performed by attaching a new SRV, allowing the resumption of the infusion flow without delay. Clinical simulation testing of 371 SRV devices demonstrated 91.9% device dislodgement prevention across all test groups and scenarios.

During connection and infusion of IV solutions, the tubing can become tangled, jerked, or pulled, causing stress on the IV catheter residing in the patient. The Orchid SRV has a therapeutic indication for PIV catheter force-activated separation of the tubing and catheter connection. The SRV separation protects the patient by causing the SRV connected to the IV tubing to separate when the average pulling tension exceeds the average threshold of 3.25lbf. Once activated, the flow pathway to both the IV tubing and catheter are aseptically sealed and locked by each half of the separated device, preventing microorganism contamination, bleeding, fluid, or medication loss, while releasing the pressure on the catheter that often causes catheter displacement from excessive pulling on the tubing and catheter. The SRV connects via a standard male Luer connection. The SRV will activate a breakaway event when the longitudinal tension threshold is exceeded, automatically closing the flow path to the catheter and administration set. Following activation, a component of the SRV is left attached to each side of the infusion system

to protect the intraluminal pathway. A new SRV is attached with each device separation.

4. Performance standards

Stress testing was performed for simulation of clinical conditions, which included connection to IV fluid administration tubing, use of commercially available securement devices, and application in porcine skin. Performance was tested for force activation and separation sealing. Catheter dislodgement was defined as the complete removal of the catheter from the skin. Delamination was defined as loss of dressing adherence with complete or partial peeling off the skin. For purposes of the study, catheter failure requiring a new dressing was defined as the replacement of the IV catheter, securement device, tape, and transparent dressing, when applicable, to the test case. Samples of the SRV consisted of ethylene oxide (EtO) sterilized, non-aged ($T = 0$), and real-time samples aged 1.8 years. By spacing the age range at both ends of the aged spectrum, the largest reflection of real-world potential usage was achieved. The study also examined the effect of securement on the IV catheter and administration tubing with both transparent dressing, and transparent dressing with securement.

Stress testing measured exerted forces on 371 SRV devices for directional opposition (tension variations applied to x, y, and z directions), against the IV securement, and for differing pull speeds. The Lab testing revealed that IV catheters dislodge with minimal pull pressure within a range of 1 to 8 lbf based on tension in current published literature [19]. The speed the IV tubing was pulled had a marginal difference in preventing dislodgement. Pulling more slowly resulted in higher separation forces. IV dislodgement was prevented by 88.3% by pulling slowly at 20 in/min. Moving more than four times faster, at 94 in/min, resulted in an IV dislodgement prevention of 95.6%. The SRV prevented IV dislodgements by 91.9% across various scenarios and all test groups in which the device separated, with no occurrences of device dislodgement. The average separation force was 3.25 lbf, within the established regulatory required force range of 1–4.2 lbf, with a standard deviation of 0.36 lbf. Final separation forces for all dressing and securement testing with the true functional window ranged from 2.09 lbf to 4.2 lbf.

5. Safety and complications

The Orchid SRV is a nonmetallic, silicone, and polycarbonate device used with peripheral intravenous catheters as an intravenous catheter force-activated separation device. The SRV is protected under Federal legend law as a prescription device intended for use by clinicians and clinical personnel, mainly nurses, trained to perform IV medication or fluid administration for use with peripheral IV catheter applications. The risk without the SRV device is higher for catheter dislodgement and failure. The SRV device functions to ensure safety without any device-associated complications. Used during intermittent and continuous infusions, patient infusion-related mechanical complications are avoided with device activation. The SRV, as shown in Figure 3, connects via a standard Luer connection between the existing administration set and extension set on a patient, allowing flow during IV therapy. The SRV is designed for patient protection allowing the device to separate into two halves when longitudinal tension exceeds the SRV tension window, automatically closing the flow path to the IV extension set and IV administration set. Following separation, a component of the SRV is left attached to each side of the infusion system to protect the intraluminal pathway. Upon separation, replacement with a new SRV is necessary to reestablish the infusion flow. The risk with the device is negligible and only associated with failure to change the SRV once activated. The SRV should be replaced per institutional policy or at least every seven (7) days.

Usability and functional testing were performed establishing safety with clinical simulation, microbial ingress, Luer-Lock, particulate, tensile strength air and water leakage and validated according to international standards and performance requirements. Aseptic technique is always used with the Orchid SRV. If a force tension event occurs, the SRV will activate, leaving each half of the SRV attached to either side of the infusion system. Upon necessary replacement of the SRV, clamp the administration set; remove and discard the used SRV half remaining on the administration set. Replace with a new, prepackaged SRV and prime the SRV per facility policy and procedures, leaving the male Luer-Lock end cap in place to retain sterility during priming. Remove the remaining activated SRV half from the catheter needleless connector hub or extension set and dispose. Disinfect the access hub per institutional policy and procedures. Remove the male Luer-Lock end cap of the new SRV and repeat clockwise attachment to the catheter needleless connector hub or extension set to complete the flow circuit. Tighten the male end by twisting the clear Luer-Lock collar, minimizing the twisting action of the purple SRV body.

6. Contraindications

Orchid SRV has no absolute or relative contraindications. There are no contraindications for this SRV since it does not engage unless needed. The SRV device is not intended for power injection applications, which typically require a direct connection with the catheter rather than injection through the IV administration tubing. The safety and effectiveness of this device, when used with other types of peripheral IV dressings or securements, has not been evaluated. The SRV is designed for use with standard IV dressings, transparent film dressings, and tape. Nexcare™ First-Aid Medical Tape and 3 M Tegaderm™ 1633 Transparent Film Dressing were used in the evaluation of the Orchid SRV. The SRV is supplied as a standalone device or as part of extension and IV administration sets.

7. Alternative devices

The Orchid SRV is the first of its kind safety release valve cleared via premarket notification and is one of two devices available in the U.S.A market for the same intended use, to provide quick safe disconnection upon pull tension on IV administration catheter tubing to prevent catheter failure.

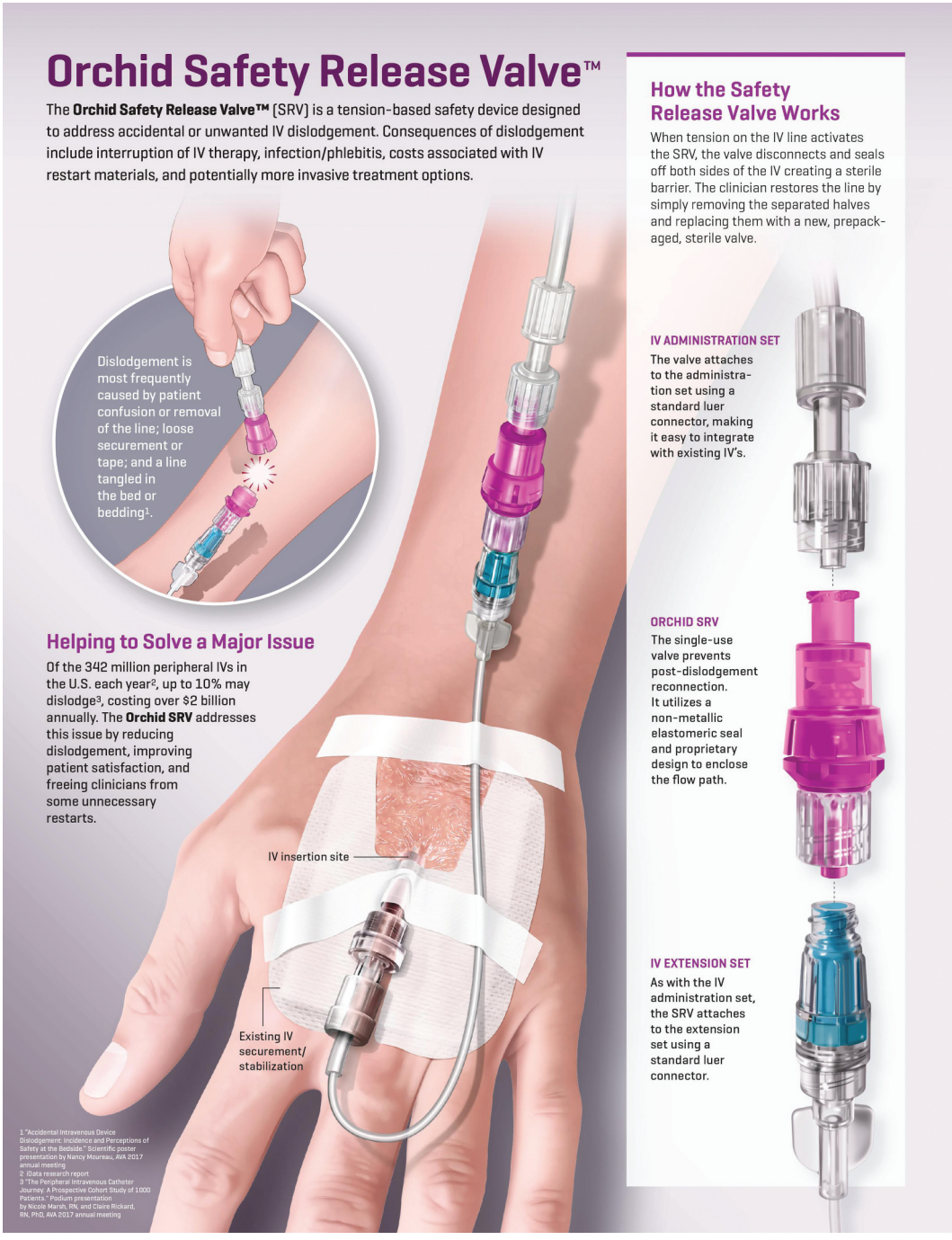

Figure 3. Infographic describing the safety features of the Orchid SRV™. Used with permission from Linear Health Sciences.

The other available device is the Safebreak® Vascular, granted via De Novo, and used as a predicate device for the Orchid SRV's premarket notification. Both devices have U.S.A indications limited to Peripheral IV and patients 18 years or older.

8. Regulatory status

The Orchid SRV is approved as a U.S.A Class of Food and Drug Administration (FDA) device for peripheral intravenous catheter indication in patients 18 years of age or older to mitigate the occurrence of mechanical complications (21 CFR 880.5220). The Orchid SRV is intended for use with electronic IV pumps in peripheral IV applications where tension may act on the IV tubing. The Orchid SRV was cleared under 510(k) K212064, product code QOI. Preceding this clearance were 2 Q-Submissions for De Novo (Q200886 and Q200886/S001), and a prior 510(k) through a third-party reviewer that resulted in an NSE (K200336). A pre-EUA application was also submitted in September 2020. Canadian clearance established indications for pediatric and multi-IV catheter use (License Number 106,356) as of July 2021. European Union (EU) mark execution for indications, reflective of Canadian usage for pediatric use with no IV site restriction, is slated for formal submission in 2023 following necessary Medical Device Regulation (MDR) audit execution.

Figure 4. Patient safety features of the Orchid SRV™. Used with permission from Linear Health Sciences.

9. Cost and value perspective for healthcare

Dislodgement of IV catheters contributes to rising healthcare costs. Of the over 340 million peripheral catheters purchased each year, a high percentage fail due to dislodgement [13,17,18,20]. Dislodgement of IV administration sets and IV catheters represents an ongoing economic issue in acute care, even when catheter securement is in place. In one recent hospital study they documented the catheter dislodgement incidence of up to 24% with an average cost of $50 US Dollars to replace the IV catheter, a typical 200-bed facility could have a cost of up to $2500 per day or up to $912,500 annually, not including the cost of other complications associated with dislodgement [9,14,21]. Total accidental IV dislodgement events are estimated to affect more than 75 million catheters annually [3,9,17,22–24]. This level of complications for with all U.S.A hospitals translate to an annual estimated cost of more than $1.8 billion. Significant healthcare savings can be realized if even a small percentage of dislodgement is reduced.

10. Conclusion

Accidental dislodgement of vascular access devices, especially peripheral catheters, is a common occurrence that warrants increased awareness of the need for safety to protect patients from unnecessary catheter failure and associated complications. By adding a simple accessory that attaches to the IV catheter and IV administration set, more than 88% of catheter dislodgements from pull force tension can be avoided.

11. Expert opinion

As a clinician active in the provision of patient care, the performance of research, and legal expert record review, I am aware of incidents of IV catheter dislodgement resulting in patient exsanguination and death. If the simple fix of a safety release valve had been installed on the IV administration set tubing of these patients, they may still be alive today (Figure 4). In my research, clinicians reported high catheter failure rates in peripheral catheters, with the most common causes of dislodged catheters from confused patients, patient intentional removal of the IV catheters, and loose transparent dressings [13]. Catheter failure from accidental dislodgement most often results in the need to replace the catheter, adding repeated insertions with risk of needlestick injury, patient trauma, and vein depletion. Prevention methods for catheter dislodgement and failure include devices such as the SRV, functioning to prevent catheter loss in all these pull-force events.

While outside of the current U.S.A Food and Drug Administration indications of peripheral intravenous catheters for patients 18 years and older, the pediatric population is especially problematic for accidental dislodgement since children are very active and like to play, even older children pull on the IV tubing connections often causing dislodgement. The pediatric population has the highest risk of dislodgement and the greatest inherent need for IV tubing-installed safety valves, as supported by the literature reporting dislodgement [11,16,23,25–27]. It is impossible for nurses to constantly monitor patients during the delivery of IV treatment.

Central venous catheters also represent a high risk of accidental dislodgement owing to the larger catheter size, higher pressure for the central vein site of insertion, and greater mortality associated with air emboli. Central catheters are not included in the SRV indications. The SRV would contribute to infection prevention with central venous catheters and all vascular access devices, by maintaining a closed system, even when the IV administration tubing interruption is needed. The immediate sealing action of the SRV, activated during the separation of the tubing from longitudinal tension application, protects the catheter and tubing until reconnection occurs.

Since the cost associated with catheter failure and restarts represents a huge loss annually for the U.S.A, not only are catheter dislodgements a patient safety issue but an economic issue as well [3]. The ability to safeguard an IV from dislodgement contributes to patient safety through the provision of more efficient treatment, reduced complications, timely

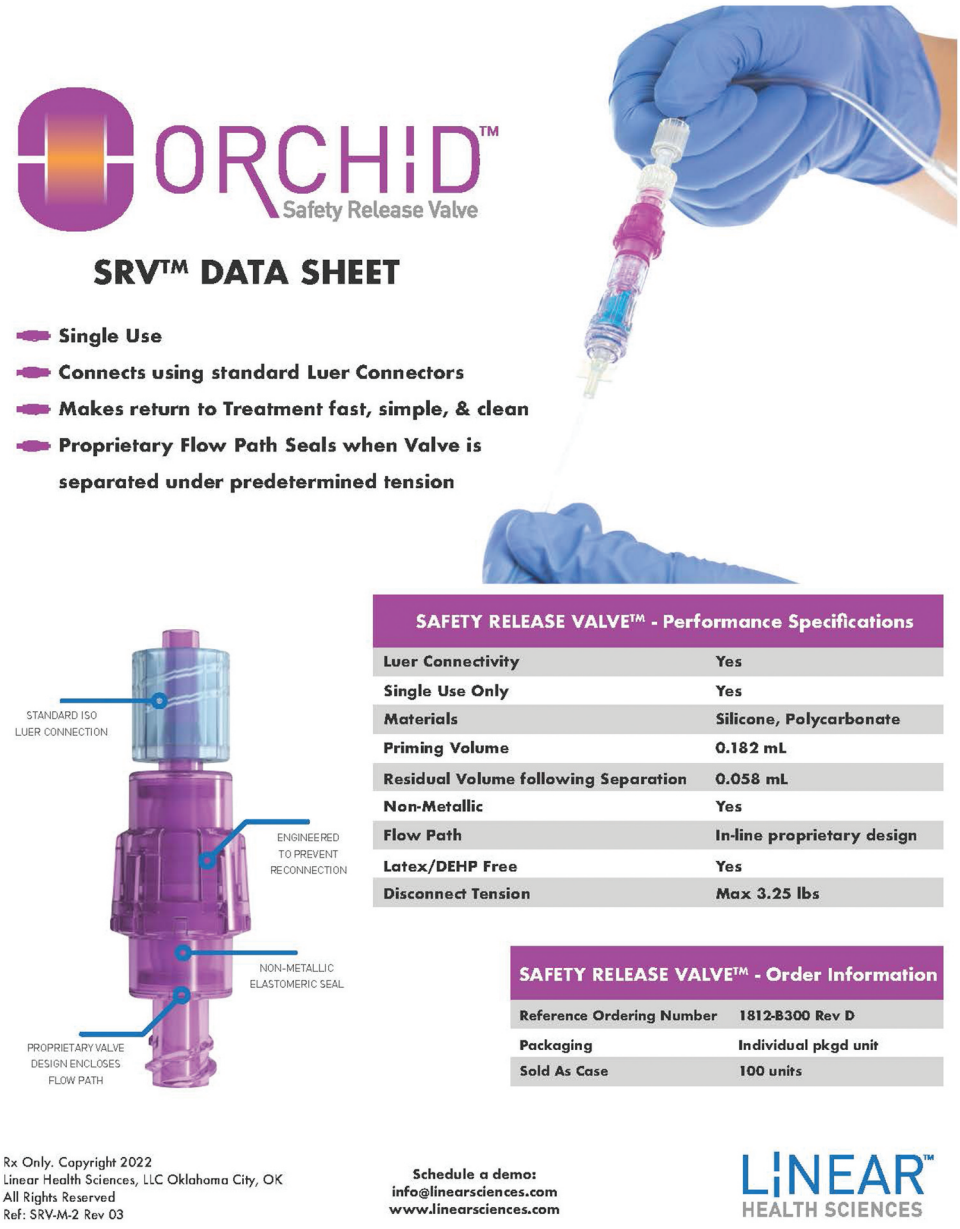

Figure 5. The Orchid SRV™ Data Sheet. Used with permission from Linear Health Sciences.

discharge of patients from hospitals, and cost savings while preserving veins and maintaining reliable IV access for the delivery of necessary medical treatments. More research is needed to validate the value and contribution of these safety release valves (Figure 5) in relation to patient safety and complication avoidance.

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Declaration of interest

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