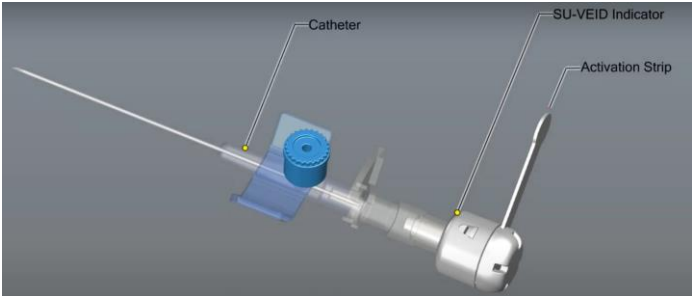



Use of Introvein attached to intravenous needle catheter to improve peripheral venous access success in venous access

<p>Title</p>	<p>Use of Introvein attached to intravenous needle catheter to improve peripheral venous access success in venous access</p>	
<p>Problem to solve</p>	<p>Intravenous access is among the most basic and frequently applied procedures in the medical profession. The process is often time consuming and tedious, and is characterized by multiple failure of access, and multiple misposition of the cannula out of the vein. Repeated sticks cause patient discomfort, elevating costs, and frequently, significant complications occur. Intravenous access is technically difficult because of the small diameter, inability to feel or see the veins, misleading blood viewed in the flashback chamber in case the needle’s tip already punctured the distal vein or retracted, or other difficult vein issues.</p>	
<p>Device Objectives</p>	<p>The purpose the Introvein™ is to increase success rate of peripheral intravenous starts, in comparison to the conventional method of vein entry techniques.</p>	
<p>Device Description</p>	<p>The Introvein is an electronic pressure sensing device, integrated to a needle catheter, and which indicates continuously along intravenous cannulation procedure: whether the tip of the needle is inside or outside of a vein, to assist a clinician in intravenous cannulation.</p> <p>The company does not sell the intravenous needle catheter. The nurse assembles (1) the sterilized intravenous catheter supplied by the hospital’s approved brand and (2) the Introvein which is supplied in a sterile pouch by Angie Technologies.</p>	
<p>Indication for Use</p>	<p>The Introvein is used to indicate the location of the vein (in relation to a tip of a needle): including indication of vein entry, vein double puncture (infiltration), vein re-entry and vein exit of an intravenous catheter system’s needle.</p>	
<p>Product Pictures</p>		
	<p align="center">When attached to intravenous needle catheter</p>	<p align="center">Introvein</p>

Device Description

The Introvein is a vein entry indicator device. This electronic and algorithm-controlled, pressure-sensitive device is tiny and integrated into the flash chamber of an IV catheter. The device signals with beeps and lights instantly upon entering the vein lumen and continues signaling as long as the needle's tip remains within the vein. After exiting the vein (either backward or forward), the device signals again once the needle's tip re-enters the vein. Thus, the Introvein aids in venous lumen entry and alerts clinicians if the needle strays outside the lumen during insertion. It is faster and more sensitive than to see blood in the flash chamber, potentially improving stick success.

Problem Worth Solving

Annually in the US, hundreds of millions of IV placements are performed. Nurses and physicians face the challenges and stresses of vascular access. Improving first-attempt success is crucial to reduce vessel injury, pain from multiple insertions, the risk of catheter-related blood infections, staff needle stick injuries, costs, and increase patient satisfaction.

Clinical risks of IV procedures include:

- **Vessel Injuries:** Damage to blood vessels. An injured or punctured vein can't be used again for some time, which may affect later treatments during a hospital stay.
- **Inflammations:** Swelling and irritation in the area where the IV is inserted.
- **Increased Risk of Infections:** Higher chance of infections related to the catheter (the tube inserted into the vein).
- **Higher Risk of Needle Stick Injuries for Nurses:** Nurses may accidentally injure themselves with the needle.
- **Medication Administered Outside the Vein Causing Tissue Damage:** If medicine is injected outside the vein, it can harm surrounding tissues.
- **Delay in Medication and Nutrition:** Challenges in setting up the IV lead to delays in administering the necessary medication and nutrition (if the IV is used for feeding).

Clinical Benchmark

The average number of IV start attempts is >2 in the general population and ≥ 3 in patients with difficult venous access. IV placement failures occur up to 50% of the time before the IVs fulfill their intended use.

Clinical Background

Venipuncture, used for intravenous therapy or venous blood sampling, is commonly performed by medical practitioners, including physicians, nurses, medical technicians, paramedics, or phlebotomists. This routine invasive procedure serves various purposes, such as diagnostic blood sampling, administering treatments, or collecting blood for later use.

The conventional method of placing the catheter into a blood vessel is using over-the-needle catheter technique (As seen in picture, the needle is resting within the catheter lumen, and the tip of the needle is stand out a little to enable the puncture of the skin), comprises skin puncture with an introducer needle, moving the needle in surrounding tissues forward towards the targeted blood vessel, puncturing the wall of a targeted blood vessel, and pushing a lumen cannula inside the targeted blood vessel while removing the needle, then throwing the needle into a safety can.



Successful performance relies on knowing when the needle enters or exits the vein, typically indicated by visual observation of blood flow to a flashback chamber or reservoir.

This process can have variable success due to factors like venous pressure, volume status, puncturing of the distal wall of the vein, and potential for misplacement.

Incorrectly placed IV catheters can cause complications like infiltration, hematoma, tissue damage, nerve damage, phlebitis, extravascular drug administration, thrombosis, delayed treatment, catheter-related bloodstream infection, and vein loss, making the patient a difficult vascular access case.

Alternatives: Use of ultrasound and Vein Visualization Techniques:

Improvement strategies, like ultrasound and other vein visualization techniques, can yield inconsistent results due to varying skill levels, and technological limitations. Furthermore, they do not signal or approve the required output that the needle is resting in the vein:

1. These technologies are employed to assist healthcare professionals in locating veins, particularly in patients where veins are difficult to access (like in individuals with small or deep veins, or those with a lot of subcutaneous fat). Ultrasound provides real-time imaging, allowing for better visualization of veins.
2. Inconsistency Due to Skill Level: The effectiveness of these techniques can vary greatly depending on the skill and experience of the healthcare provider. Ultrasound, for instance, requires a certain level of expertise to correctly interpret the images and guide the needle into the vein.
3. Technological Limitations: Despite advancements, these technologies are not foolproof. They may not always provide a clear or accurate assistance, especially in certain patient groups (like those with edema or scar tissue). The quality of the equipment and its resolution also play a crucial role.
4. Lack of Confirmation of Needle Placement: One significant limitation highlighted is that while these technologies can aid in locating the vein, they don't necessarily confirm that the needle

has successfully exited or entered or reEntered the vein, and this can lead to a failure and multiple attempts.

5. **Cumbersome and Limited Mobility:** Many of these devices, particularly ultrasound machines, are bulky and not easily portable. This can be a significant issue in settings where mobility is even more essential, such as in emergency rooms, during field medical services, or in bedside care in hospitals, or ambulances. The lack of portability can limit the utility of these devices in various clinical scenarios.
6. **Cost Implications:** These technologies are also generally costly. The initial investment in the equipment can be significant, and there may be ongoing costs related to training, and potentially consumable components. In healthcare settings where budget constraints are a concern, the high cost per use of these devices can be a limiting factor, potentially impacting the decision to use these technologies, especially in less critical situations or in facilities with limited resources.

Duration

- The IV procedure usually takes a few minutes, but sometimes it can last up to an hour and more.
- Delays in IV start due to failures may delay the infusion in hours.
- After a set period, as per the hospital's rules, the nurse will check to make sure the infusion is working properly.
- If the catheter is placed incorrectly and this is only discovered during the nurse's check-up, which might happen two hours later, it means the infusion has been delayed by at least two hours.

Need for Improvement:

There's a need for more advanced technologies or methods that not only assist in visualizing veins but also confirm successful cannulation (the process of inserting a cannula into a vein). Such advancements could potentially increase success rates, reduce patient discomfort, and improve overall outcomes in IV therapies. Moreover, it may assure the final position of the cannula in the vein.

Detailed Description of the Introvein

The Introvein is a sterile, disposable device indicating the position of a needle's distal end relative to a patient's blood vessel, detecting and indicating intravascular catheter entry and exit. It attaches to the catheter's proximal end, fluidly connecting its lumen to a pressure sensor. This sensor responds to pressure changes within the needle, finding signals by an adaptive algorithm, which are then indicated by sound and light emitters. The device instantly identifies catheter penetration of blood vessel walls by analyzing pressure histories and changes, offering immediate response to prevent double puncturing (infiltration) and ensuring correct needle positioning. The Introvein's instant feedback to all events, distinguishing it from conventional catheters, allows clinicians to react immediately and confidently,

reducing the risk of missing the vein or double puncturing. This capability increases the likelihood of successful IV placement on the first attempt.

Benefits of the Introvein

The Introvein device may benefit subjects by reducing the attempts, easing, and quickening the IV catheterization procedure, thereby reducing exposure to risks.

- Patients can benefit from the Introvein if it makes the IV procedure faster and more efficient.
- The device may help avoid multiple needle insertions, reducing discomfort for the patient.
- By minimizing risks like vessel injury and infections, the Introvein also helps avoid potential complications.
- Hospitals may save on costs associated with these risks, such as treating infections or injuries resulting from multiple attempts at IV insertion.
- The Introvein is simple, intuitive, and accurate, enhancing the ease of the procedure. It is attached to the catheter and is disposable, aligning with standard medical safety practices. The device is placed on the nurse's standard cart with other disposables, making it easily accessible. This allows nurses to use it readily instead of needing to call physicians for assistance or using a cumbersome ultrasound trolley.

Risks

The Introvein is a low-risk device. Its structure and operational principle minimize the likelihood of adverse reactions and hazards due to malfunction. In worst-case scenarios, standard blood return indications remain a fallback.

Any adverse reactions observed will be recorded and reported, according to risk management procedures, and assessments performed according to ISO 14971 (2007).


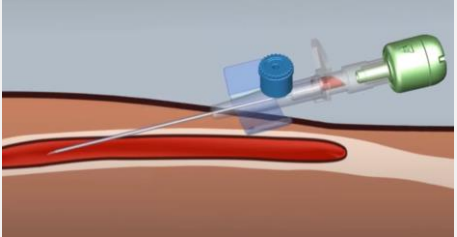
- There are no known additional risks using the Introvein compared to the standard method of IV insertion.
- The worst-case scenario with the Introvein is not worse than the risks already present in standard procedures.
- Nurses routinely check for blood flow in the needle's flashback window in all procedures, with or without the Introvein. They use the same criteria to confirm that the cannula is properly placed in the vein. The Introvein helps quickly locate the vein, but the final decision about the needle's

position is based on hospital procedures, which include checking for blood flow in the final position.

- If the Introvein malfunctions, for example by worst case scenario of indicating the needle is in the vein when it's not, it's similar to a nurse misjudging a misleading blood signal. In any case, the nurse must confirm seeing blood in the flashback window and observe blood flow. A practitioner may also verify, according to its hospital regulations, the correct vein placement by injecting saline with a syringe after the procedure, ensuring that the saline injection does not cause swelling in the tissues around the anticipated cannula location.

Comparison of the Introvein to a conventional IV and the procedure

	Conventional Methods	Introvein
Preparation	Pull the needle catheter from a sterilized cover	Pull the needle catheter from a sterilized cover, then pull the Introvein from a sterilized cover and connect to each other' Luer connector. Then, pull out the activation strip
Stick the skin surface in a preferred location	Same action	Same action
Vein- entry indication	Visual indication-Blood appears in Flashback chamber. Response time Average of 1 sec (max is up to 4sec.)	Audible/light beep activated by Pressure sensor, response time: - 0.1 second then blood appears in the flashback window.
Vein-exit indication	Once the flashback chamber if filled with blood there is no easy way to detect a reliable indication of needle	Exit Indication by audio/light signal

	exit, such as double puncture, from vein.	
In-vein indication	 <p>There is a blood in the flashback chamber but no assurance that the needle is STILL in-vein</p>	 <p>The light and beep indications assure that needle tip is resting in-vein.</p>
Vein re-entry	Once the flashback chamber if filled with blood there is no easy to detect and reliable indication of needle re-entry to vein.	Vein entry indication resumes
Ongoing feedback	Once the flashback chamber if filled with blood there is no easy to detect and reliable indication.	Ongoing feedback throughout the procedure means needle may not be 'misplaced'.
Procedure finalizing	View blood flow in the cannula	View blood flow in the cannula, continuous entry audio/light
Sterilization	Sterilized needle catheter.	Sterilized device.
User- friendly	Practitioner focus is divided between point of entry and flashback chamber.	Allows full focus on point of entry.
Number of attempts factor	More than 2 attempts in general population. More than 3 attempts in difficult patients (DIVA).	Reduce number of attempts due to instant indication and higher assurance.

Time factor	Costly, tedious, risky and unpleasant retrials are often required.	Ongoing feedback feature increases likelihood of smooth quick and safe insertions-the first time.
Risks	Risks due to multiple attempts and time of exposure to risks.	Reduced risks due to fewer attempts and shorter time of exposure.

Procedure Summary

1. Purpose:

- The IV procedure is used to administer medicine directly into the bloodstream.
- The procedure involves using the Introvein device to insert a cannula into a vein, a standard process in hospitals. Future versions will combine the needle and Introvein into one unit.

2. Initial Steps:

- The nurse begins by locating the most suitable vein for the procedure.

3. Attachment and Insertion:

- The sterile Introvein device is attached (by the nurse) to a standard IV needle.
- The nurse then inserts the needle into the identified vein in the regular way, with no change to the standard insertion technique.

4. Introvein's Role in Successful Vein Entry:

- The Introvein notifies the nurse upon successful entry into the vein, without altering the standard method.
- This device assists the nurse in quickly verifying that the cannula is correctly placed in the vein, thereby reducing the need for additional needle insertions. The nurse is alerted to stop advancing the needle when the device beeps.

5. Feedback and Adjustment:

- The nurse listens for the beep and watches for the light from the device, which provides instant feedback to prevent multiple needle insertions.
- If the needle unintentionally exits the vein, the Introvein stops beeping. The nurse then repositions the needle until the beeping resumes.

6. Confirmation of Needle/Cannula Placement:

- The nurse confirms the proper placement of the needle/cannula by observing blood in the needle's flashback chamber.
- They may also verify the correct vein placement by injecting saline with a syringe after the procedure (Picture below). This ensures that the saline injection does not cause swelling in the tissues around the anticipated cannula location.

7. Final Steps:

- The needle is then removed from the flexible plastic cannula. The Introvein, still attached to the needle, is disposed of safely.
- The nurse secures the cannula to the patient's skin surface, completing the procedure.

Saline injection

