



DialySafe Needle

TECHNOLOGY NUMBERS: 2023-154, 2025-616

Accelerate Blue Foundry - 2025 (Life Sciences)

OVERVIEW

Our DialySafe Needle is an all-in-one patent-pending universal platform needle technology equipped with a pressure-sensitive, automated safety mechanism, needle-stick injury protection, and transparent tubing, by which we aim to significantly improve the safety and reliability of cannulation. This device with a novel needle-in-needle mechanism and automated safety backstop is designed to prevent infiltration (through and through injury through the back wall) and reduce the risk of accidental needle stick injuries—without requiring additional training or workflow changes resulting in significant cost savings.

DESCRIPTION

Our innovative solution is an all-in-one universal platform technology designed to improve the safety and reliability of vascular access. It features a novel needle-in-needle mechanism with a sharp outer needle encasing a blunt inner needle, all within a transparent housing that allows caregivers to visualize blood flow and confirm vein entry. A pressure-sensitive, automated safety mechanism retracts the sharp tip upon detecting adequate blood flow, exposing the blunt needle to prevent puncturing the far wall of the vessel—a leading cause of infiltration. The device also incorporates needle-stick injury protection, enhancing safety for both patients and healthcare staff, while maintaining seamless integration into standard hemodialysis procedures without requiring additional training.

The universal platform design extends beyond dialysis, supporting adaptation to peripheral IV applications with a similar needle-in-needle architecture and a plastic cannula for broader clinical use. This approach allows the same core technology to address high-risk cannulation challenges across multiple care settings, including pediatrics, oncology, and infusion therapy, providing a consistent, workflow-compatible solution. By combining automated safeguards, real-time procedural guidance, and broad applicability, Dialy-Safe offers a transformative solution for vascular access, improving patient outcomes, reducing complications, and enhancing provider efficiency.

Technology ID

2023-154

Category

Medical Devices

Life Sciences

Accelerate Blue Foundry -

2025/Life Sciences

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VALUE PROPOSITION

Our novel needle offers a differentiated, all-in-one solution that enhances safety, efficiency, and ease of use at lower cumulative costs:

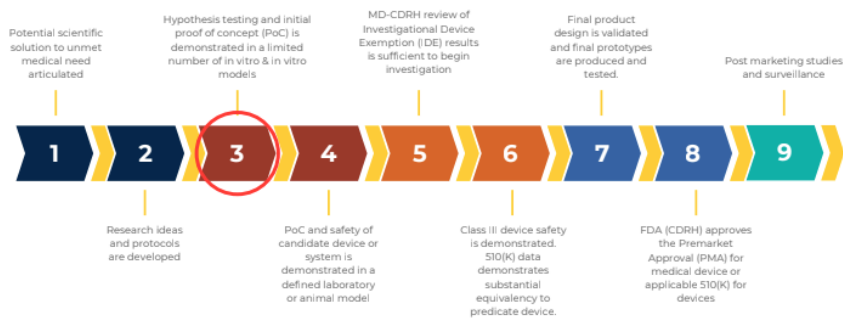
- Prevents infiltration at insertion and reduces vessel injury from patient movement.
- Integrated safety guard eliminates the risk of accidental needle stick injury.
- Automated functionality—no need for ultrasound support or user activation.
- Seamless clinical integration -No workflow changes or additional training required
- Cuts down on unnecessary health care expenditures.

This device uniquely combines clinical protection with seamless adoption, delivering value to both patients and providers.

TECHNOLOGY READINESS LEVEL

Explore other available products test at [University of Michigan](#)

Medical Device Technology Readiness Levels



INTELLECTUAL PROPERTY STATUS

Our team has secured two provisional Patents (No. 63/607,195, Ref. No.: 2023-154-02, and No. 63/816037, Ref. No.: 2025-616-01) filed on December 7th 2023 and June 2nd 2025, respectively, and a non-provisional patent conversion (Ref. No.: 2023-154-04, PCT/US2024/044709), filed August 30th 2024.

MARKET OPPORTUNITY

Dialysis cannulation errors drive more than 2 million infiltration events annually in the U.S., costing the healthcare system over \$1 billion per year in avoidable complications. With 37 million Americans living with Chronic Kidney Disease (CKD) and over 600,000 on hemodialysis, vascular access is both the lifeline as well as achilles heel of dialysis and remains the single most critical — and vulnerable — element of dialysis care. Dially-Safe directly addresses this problem by improving cannulation accuracy, reducing complications, and lowering costs for providers and payors.

The U.S. dialysis needle market represents a \$1.36B total addressable market, with a \$663M obtainable market in high-risk patients such as those with difficult access, on home dialysis, or living with disabilities. The market is projected to grow at ~9% annually, with strong pull from regulators and employers focused on safety and efficiency. Beyond dialysis, Dially-Safe is positioned to expand into the \$5.5B peripheral IV access market (growing to \$10.6B by 2033) as well as pediatrics, oncology, and infusion therapy.

Extensive customer discovery through I-Corps and external consumer market research via the Coulter Translational Research Partnership confirm the strong demand from all stakeholders clinicians, dialysis organizations, and patients for safer, more reliable vascular access solutions. This validation supports both the clinical need and the commercial viability of Dially-Safe.

With a cost-efficient, scalable design, a clear FDA 510(k) regulatory pathway, and active engagement with strategic partners (BD, Terumo, Quest), Dially-Safe is positioned to rapidly scale from prototype to global commercialization, capturing significant share in a growing market while setting the standard for next-generation vascular access.

HUGE PAIN & HUGE IMPACT



"The infiltration is very **painful**... my arm was **extremely swollen**."

Joan, Patient



"Infiltration can be **life-threatening**."

Dr. Rachel Perlman,
Nephrologist



"I hate injuring patients...I wish I had a **better needle**."

Nate R., Dialysis
Technician



"This needle would be a **gamechanger** for young patients, especially in the ICU."

Dr. Weiwen Shih,
Pediatrician



100% of Interviews
love this idea

Customer Discovery Learning

Additional value->	Old, young and new-inclusive	Avoids dislodgment	Premium pricing	Novice end user	Universal platform technology
Nurses	✓✓✓✓	✓✓✓✓	---	✓✓✓✓	✓✓
Doctors	✓✓✓✓	✓	✓✓✓	✓✓✓✓	✓✓
Experts	✓✓✓✓	---	✓✓	✓✓	✓✓



100% of Interviews
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