Novel Comprehensive Apical Cardiac Access Device for Acute Resuscitation of the Injured Warfighter

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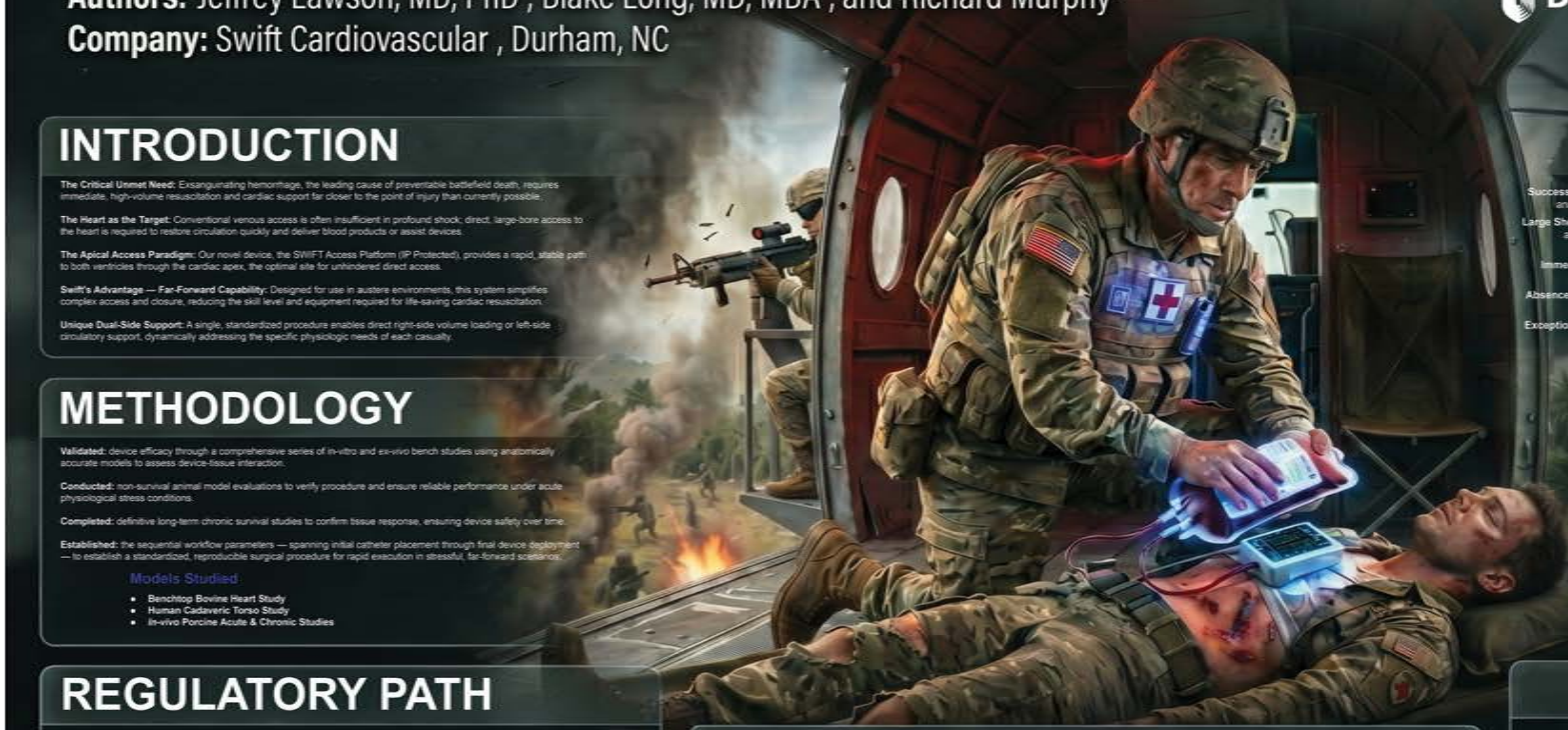


INTRODUCTION

The Critical Unmet Need: Exsanguinating hemorrhage, the leading cause of preventable battlefield death, requires immediate, high-volume resuscitation and cardiac support far closer to the point of injury than currently possible.

The Heart as the Target: Conventional venous access is often insufficient in profound shock; direct, large-bore access to the heart is required to restore circulation quickly and deliver blood products or assist devices.

The Apical Access Paradigm: Our novel device, the SWIFT Access Platform (IP Protected), provides a rapid, stable path to both ventricles through the cardiac apex, the optimal site for unhindered direct access.

Swift's Advantage — Far-Forward Capability: Designed for use in austere environments, this system simplifies complex access and closure, reducing the skill level and equipment required for life-saving cardiac resuscitation.

Unique Dual-Side Support: A single, standardized procedure enables direct right-side volume loading or left-side circulatory support, dynamically addressing the specific physiologic needs of each casualty.

METHODOLOGY

Validated: device efficacy through a comprehensive series of *in-vitro* and *ex-vivo* bench studies using anatomically accurate models to assess device-tissue interaction.

Conducted: non-survival animal model evaluations to verify procedure and ensure reliable performance under acute physiological stress conditions.

Completed: definitive long-term chronic survival studies to confirm tissue response, ensuring device safety over time.

Established: the sequential workflow parameters — spanning initial catheter placement through final device deployment — to establish a standardized, reproducible surgical procedure for rapid execution in stressful, far-forward scenarios.

Models Studied

- **Benchtop Bovine Heart Study**
- **Human Cadaveric Torso Study**
- ***In-vivo* Porcine Acute & Chronic Studies**

RESULTS

Successful Specimen Access: Demonstrated platform deployment and wire navigation across multiple complex anatomical models, including bovine and human cadaveric hearts, confirming baseline geometric feasibility.

Large Sheath Access Without Surgery: Successfully achieved large sheath access (20F) through the ventricular apex in large animal models, completely obviating the need for a traumatic open cut-down thoracotomy or sternotomy.

Immediate Mechanical Hemostasis: Achieved a total hemostatic seal once the sealing device was deployed, demonstrating immediate mechanical security in high-pressure ventricular zones.

Absence of Electrical Irritability: Encountered no significant or adverse arrhythmias during *in-vivo* manipulation, validating that the ventricular apex has minimal electrical irritability and is tolerant to the procedure.

Exceptional Chronic Integrity: Confirmed structural stability after 30-day *in-vivo* with complete tissue integration.

CONCLUSION

Proof-of-concept (POC) of our novel heart access platform was established in bovine and human cadaver hearts and in chronic *in-vivo* porcine studies.

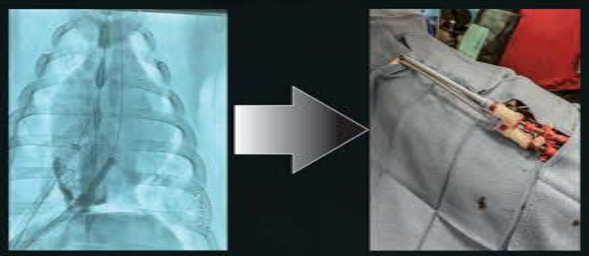
Deployment of the SWIFT Access Platform in far-forward combat theatres could provide immediate circulatory support, reduced time in shock, and faster recovery for the injured warfighter.

REGULATORY PATH

COMPONENTS: CATHETERS, SHEATHS

FDA SUBMISSION: IMPLANT DEVICE

CLINICAL WORKFLOW



TEAM

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