SUMMARY STATEMENT

PROGRAM CONTACT:
[redacted]

(Privileged Communication)

Release Date: 03/04/2026
Revised Date:

Application Number: 1R43EB134892-01

Principal Investigators (Listed Alphabetically):
[redacted] (Contact)
[redacted]

Applicant Organization: [redacted]

Review Group: ZRG1 SBIB-S (18)
Center for Scientific Review Special Emphasis Panel
Small Business: Instrumentation and Bioengineering Sciences

Meeting Date: 02/05/2026
Council: MAR 2026
Requested Start: 09/01/2026

Opportunity Number: PA-24-246
PCC: EBS -SO

Project Title: AI-Guided Robotic Microsurgical System for Autonomous Suturing in Minimally Invasive Cardiac Procedures

SRG Action: Impact Score:45
Next Steps: Visit https://grants.nih.gov/grants/next_steps.htm
Human Subjects: 10-No human subjects involved
Animal Subjects: 30-Vertebrate animals involved - no ass. conditions noted
Participant Sex:
Participant Race and Ethnicity:
Participant Age:
0-No human subjects

Project Year	Direct Costs Requested	Estimated Total Cost
1	256,000	317,440
TOTAL	**256,000**	**317,440**

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

1R43EB134892-01 [redacted]

RESUME AND SUMMARY OF DISCUSSION: The committee recognized the potential significance of autonomous robotic suturing in cardiac surgery but expressed substantial concerns about the approach. The technology is at a very early stage of development, with limited preliminary data demonstrating only phantom tissue testing. The AI algorithm for autonomous decision-making during suturing has not been validated in any biological tissue model. The pathway to clinical translation is unclear, and the regulatory strategy for an autonomous surgical robot is not adequately addressed. The team has relevant engineering expertise but lacks clinical surgical collaborators with experience in robotic cardiac surgery.

- The concept of AI-guided autonomous suturing addresses a genuine technical challenge in minimally invasive cardiac surgery.
- The technology is very early-stage with insufficient preliminary data to support the proposed Phase I objectives.
- The AI algorithm has been tested only on synthetic phantoms with no biological tissue validation.
- The regulatory pathway for autonomous surgical decision-making is highly uncertain and not adequately addressed.
- The team lacks clinical collaborators with direct experience in robotic cardiac surgery.
- Commercialization concerns were significant.

DESCRIPTION (provided by applicant): This Phase I SBIR application proposes to develop and validate an AI-guided robotic microsurgical system capable of autonomous suturing during minimally invasive cardiac procedures. The system integrates computer vision, force-sensing feedback, and deep learning algorithms to plan, execute, and verify suture placement without direct surgeon manipulation. Phase I will demonstrate autonomous suturing accuracy in ex vivo porcine cardiac tissue models, with success defined as achieving suture placement accuracy within 0.5mm of surgeon-planned targets with tensile strength equivalent to manual suturing. Preliminary testing on silicone phantom models demonstrates suture placement accuracy of 0.8mm with a completion rate of 72% across 50 test sutures.

PUBLIC HEALTH RELEVANCE: Minimally invasive cardiac surgery reduces patient recovery times and complications compared to open procedures, but the technical demands of microsurgical suturing through small access ports limit adoption. An AI-guided robotic system that can autonomously execute precise suturing could expand access to minimally invasive techniques and improve outcomes.

CRITIQUE 1

Significance: 3

Investigator(s): 5

Innovation: 3

Approach: 7

Environment: 3

Overall Impact: This application proposes development of an AI-guided robotic system for autonomous cardiac suturing. While the concept is interesting, the application suffers from multiple significant weaknesses. The preliminary data are limited to synthetic phantom testing. The AI algorithm is not described with sufficient technical detail to evaluate feasibility. The team lacks essential clinical surgical expertise. The regulatory pathway for autonomous surgical robots is highly uncertain and not addressed. These concerns significantly dampened enthusiasm.

1. Significance:

Strengths

- Microsurgical suturing is a genuine bottleneck limiting adoption of minimally invasive cardiac procedures.
- Surgeon fatigue during prolonged suturing sequences is a recognized patient safety concern.

Weaknesses

- Existing surgical robots (da Vinci, Hugo) provide surgeon-controlled microsurgical capability that addresses many of the same challenges without requiring autonomous decision-making.
- The clinical need for fully autonomous suturing versus surgeon-assisted suturing is not convincingly established.

2. Investigator(s):

Strengths

- The engineering team has relevant expertise in robotics and computer vision.

Weaknesses

- The team does not include a cardiac surgeon with robotic surgery experience. This is a critical gap for a project proposing to automate a surgical procedure.
- The PI has no prior experience with medical device development or regulatory interactions.
- No clinical advisory board is described.

3. Innovation:

Strengths

- Autonomous suturing with real-time force feedback and computer vision is technically ambitious.
- If successful, the technology could have applications beyond cardiac surgery.

Weaknesses

- The application does not adequately differentiate this system from existing research platforms for autonomous suturing (e.g., Smart Tissue Autonomous Robot - STAR).
- The AI architecture description is superficial and does not address critical safety considerations for autonomous surgical decision-making.

4. Approach:

Strengths

- The use of ex vivo porcine tissue models is appropriate for initial validation.
- Quantitative success criteria (0.5mm accuracy, tensile strength equivalence) are defined.

Weaknesses

- The preliminary data are limited to synthetic phantom testing (0.8mm accuracy, 72% completion rate). These results do not yet meet the proposed success criteria and biological tissue presents substantially greater challenges.
- The deep learning algorithm is described at a high level without detail on training data, architecture, validation methodology, or failure mode analysis.
- The transition from phantom to biological tissue is treated as incremental when it is in fact a major technical hurdle involving tissue deformation, bleeding, and variable anatomy.
- No discussion of safety mechanisms for autonomous system failure during suturing.
- The regulatory strategy section does not address the significant FDA challenges associated with autonomous surgical decision-making. No predicate device exists.
- The power analysis for the proposed 200-suture validation study is not provided.

5. Environment:

Strengths

- The robotics laboratory has appropriate equipment for prototype development.

Weaknesses

- No access to a surgical simulation or cadaver laboratory is described for biological tissue testing.
- No clinical site partnership is in place for future translational work.

Commercialization Plan (Phase II and Fast-Track Only):

Not applicable for Phase I only.

Vertebrate Animals:

Acceptable

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Significance: 3

Investigator(s): 4

Innovation: 4

Approach: 6

Environment: 4

Overall Impact: The concept has merit but the application is premature. The preliminary data do not yet support the proposed Phase I objectives, and critical gaps in the team (clinical surgery), the approach (regulatory strategy, safety mechanisms), and the environment (no surgical testing facility) need to be addressed before this project is ready for SBIR funding.

1. Significance:

Strengths

- Autonomous suturing could address real challenges in minimally invasive surgery.

Weaknesses

- The incremental benefit over surgeon-controlled robotic suturing is not clearly demonstrated.
- Patient safety implications of autonomous surgical decision-making require much more thorough discussion.

2. Investigator(s):

Strengths

- Relevant engineering expertise in robotics.

Weaknesses

- No clinical surgical expertise on the team is a significant limitation.
- No evidence of prior medical device development experience.

3. Innovation:

Strengths

- The integration of computer vision and force feedback for autonomous suturing is interesting.

Weaknesses

- Similar work has been published by academic groups. The novelty over existing research is unclear.

4. Approach:

Strengths

- The proposed metrics for suture quality are appropriate.

Weaknesses

- Current preliminary data (0.8mm on phantoms) do not meet the proposed 0.5mm success criterion even on synthetic materials.
- The plan to achieve 0.5mm accuracy on biological tissue within one year of Phase I is not supported by the current data.
- Safety and failure mode analysis is absent.
- Regulatory pathway is not addressed.

5. Environment:

Strengths

- Adequate robotics development laboratory.

Weaknesses

- No surgical simulation facility access.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Significance: 2

Investigator(s): 4

Innovation: 3

Approach: 5

Environment: 3

Overall Impact: The long-term vision of autonomous surgical suturing is compelling, and the significance of the problem is clear. However, the application is not yet competitive for several reasons: the preliminary data are insufficient, the team needs clinical surgical collaborators, and the regulatory pathway requires serious attention. A substantially strengthened resubmission could be competitive if these issues are addressed.

1. Significance:

Strengths

- The clinical problem is genuine and well-articulated.
- Autonomous suturing could have broad surgical applications.

2. Investigator(s):

Strengths

- Strong engineering credentials.

Weaknesses

- Critical lack of clinical surgical expertise on the team.
- A clinical co-PI with robotic cardiac surgery experience would significantly strengthen the application.

3. Innovation:

Strengths

- Ambitious and potentially transformative concept.

Weaknesses

- Must more clearly differentiate from published academic work on autonomous suturing.

4. Approach:

Strengths

- Clearly defined quantitative endpoints.

Weaknesses

- Gap between current phantom data and proposed biological tissue objectives is large.
- Safety analysis and regulatory strategy are inadequately developed.
- Would benefit substantially from including a benchtop biological tissue testing phase before the full ex vivo validation.

5. Environment:

Strengths

- Robotics lab is adequate for engineering development.

Weaknesses

- Access to surgical testing facilities needs to be formalized.

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: ACCEPTABLE.

PARTICIPANT SEX CODE: ACCEPTABLE

PARTICIPANT RACE AND ETHNICITY CODE: ACCEPTABLE

PARTICIPANT AGE CODE: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1R43EB134892-01; PI Name: [redacted]
NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW

Small Business: Instrumentation and Bioengineering Sciences

ZRG1 SBIB-S (18)

02/05/2026

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-22-044 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html, including removal of the application from immediate review.

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.