Enhancing Interdisciplinary Training through Biodesign: Development of a Tumor Margin Tracking System

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SOFT TISSUE SARCOMA RESECTION

- **Soft tissue sarcomas** (STS) are malignancies that arise in muscles, fat, nerves, and other soft tissues.
- Affects **13,590 patients annually** in the U.S.[1]
- STS recurrence rate after surgery is **40-50%.**[2,3]

CURRENT MARGIN LABELING IS INEFFICENT

- **Surgeons label** specimens intraoperatively with **sutures, clips, or dyes** to mark orientation post-resection.

These methods are often:

- ❌ **Imprecise**
- ❌ **Inefficient**
- ❌ **Inconsistent**

Misguided Pathology Interpretation ⟶ High Risk of Recurrence

Need Statement: *A way to* ***accurately mark*** *tumor margins and* ***track orientation*** *in adult patients with soft tissue sarcoma undergoing tumor resection for surgeons to* ***improve standardization*** *and* ***enhance communication.***

DESIGN CRITERIA

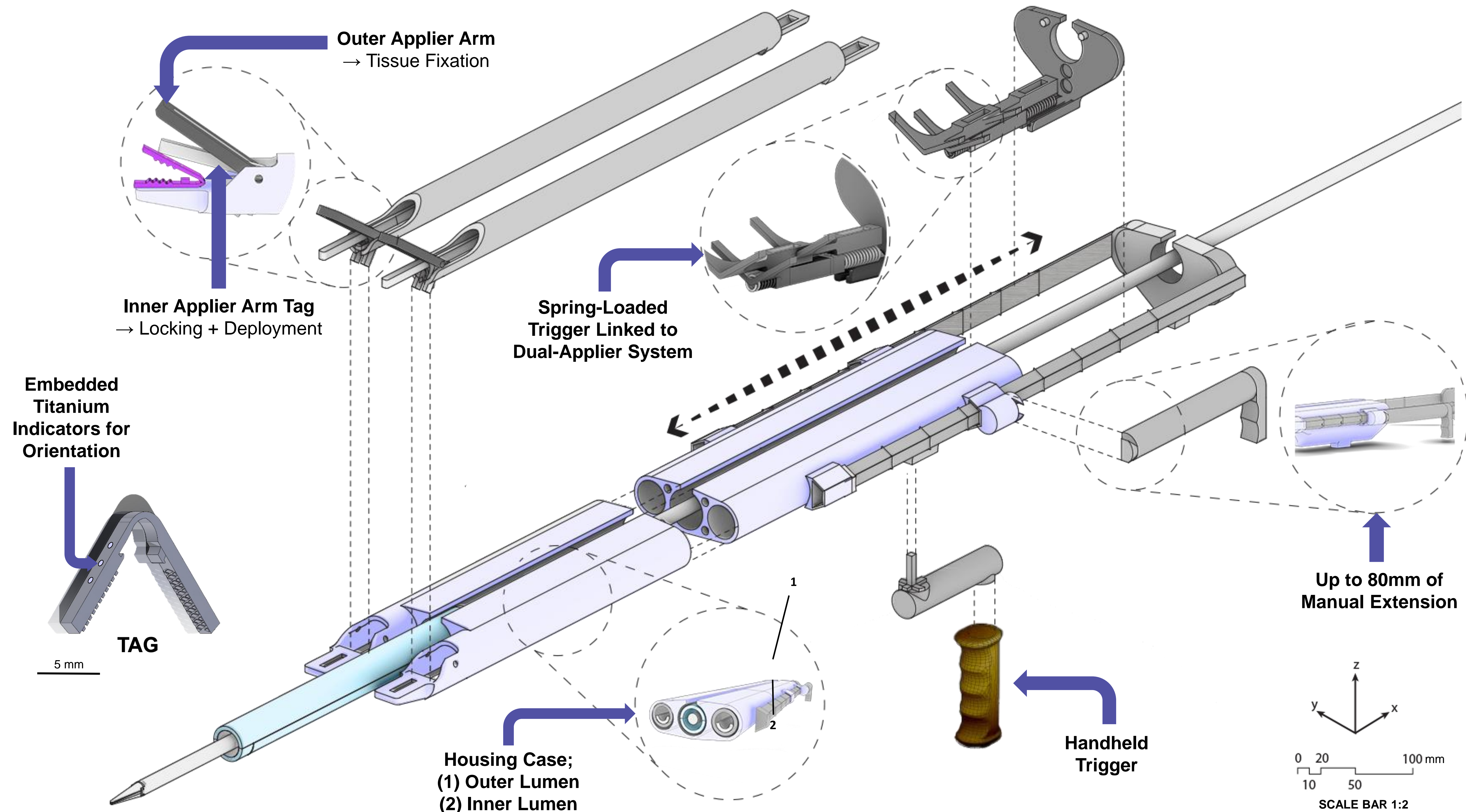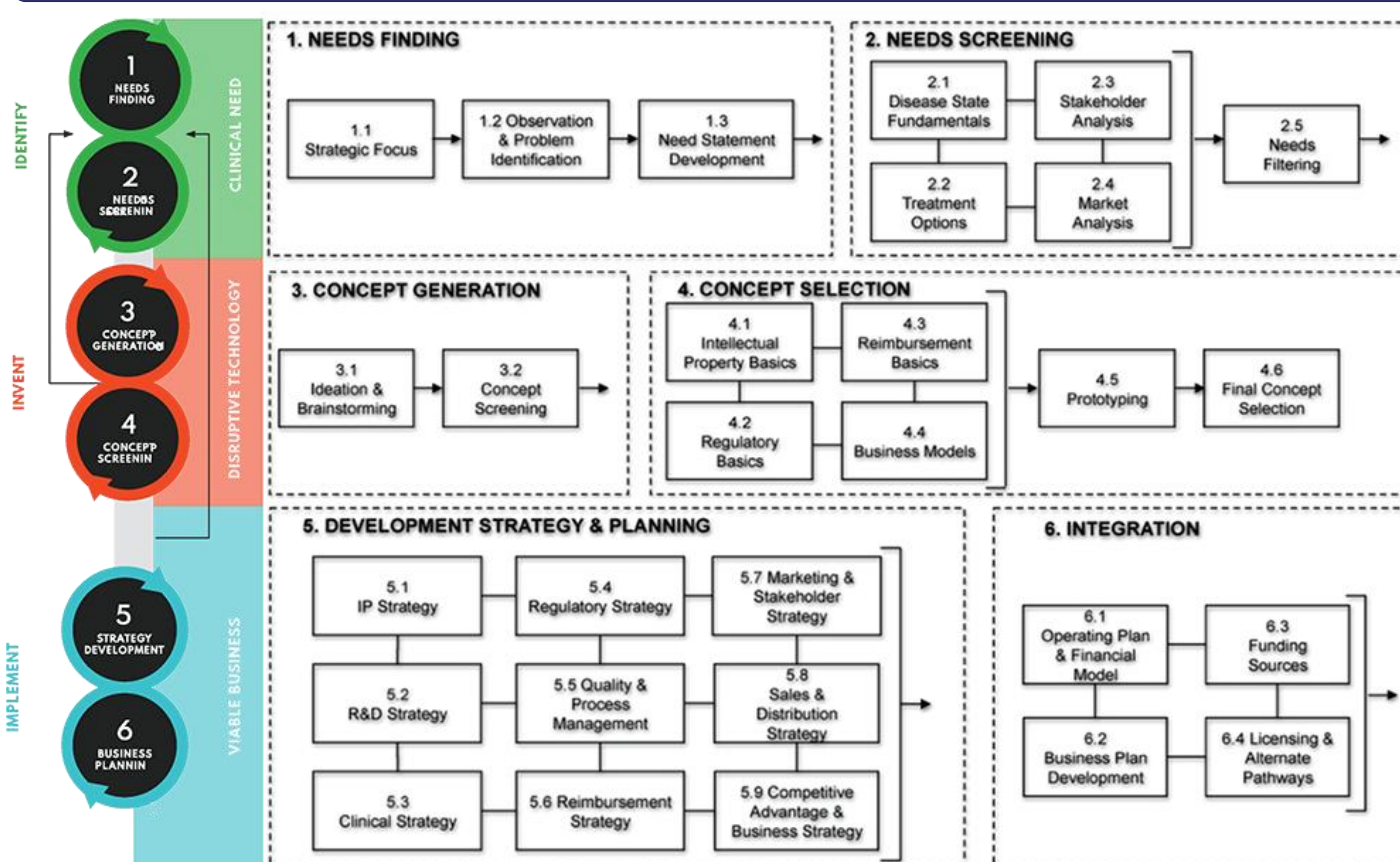| |
|---|
| Physically labels 6 primary margins and high-risk zones (HRZ) |
| Effectively orients specimen |
| Facilitates long-term surveillance (≥ 5 years) |
| Correlates specimen and defect in a 1:1 manner |
| Enhances communications between surgeons and pathologists |

DUAL-SIDED TAG APPLIER (DSTA) DESIGN

The DSTA attaches to traditional resection tools to place twin tags on adjacent margins at the point of resection.

Outer Applier Arm → Tissue Fixation

Inner Applier Arm Tag → Locking + Deployment

Spring-Loaded Trigger Linked to Dual-Applier System

Embedded Titanium Indicators for Orientation

TAG

5 mm

Up to 80mm of Manual Extension

Housing Case; (1) Outer Lumen (2) Inner Lumen

Handheld Trigger

0 20 100 mm
10 50
SCALE BAR 1:2

THE BIODESIGN PROCESS

- **Stakeholder Interviews** – 15 providers interviewed
- **Observed Current Workflow** – 3 surgeries x 4 observers
- **Established Web of Mentors** – 30+ providers, engineers, consultants, and others
- **Needs Screening Performed** – Graduate students researched 4 Pillars

- **Concept Generation** – 100+ ideas using Crawford Slip, Modified Reflection, and SCAMPER methods
- **Concept Selection** – utilized screening/scoring Pugh matrices and feasibility checks
- **Selected Concept** – DSTA – advanced to iterative prototyping, CAD modeling, V&V

- **IP Strategy** – Prior art searches performed; Provisional patent filed
- **Regulatory** – FDA Class II De Novo based on risk profile and comparable technologies
- **Payment** – Disposable purchased for $1.5K; purchased by hospitals and surgical centers; included in bundled payments for tumor resection surgery
- **Reimbursement** – CMS criteria met given cost savings and superior clinical outcomes
- **Future Steps** – Continue validation studies; Identify development and commercialization partners

IMPACT & CONCLUSION

Clinical Impact
- Tags margins at the point of resection to enhance precision and accuracy.
- Enables providers to easily relocate the prior tumor bed for targeted treatment and recurrence monitoring, facilitating timely re-intervention when necessary.

Engineering Innovation
- Validated, unique dual-tagging mechanism marks both the resected specimen and tumor bed simultaneously.
- Designed for standardization and compatibility with common surgical workflows and imaging modalities.

Educational Value
- Provided end-to-end exposure to the innovation process, from need to prototype.
- Encouraged collaboration with clinicians and engineers.

References