Team 6 - Salura Health - Reimagined Tenaculum

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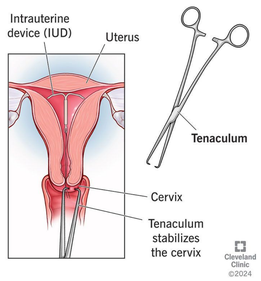
Clinical need

Current tenaculum designs frequently cause considerable pain, bleeding, and tissue trauma during gynecological procedures due to their sharp, toothed grasping ends. These adverse effects contribute to patient discomfort, anxiety, and hesitancy to undergo routine reproductive health care, including IUD insertions, biopsies, and other cervical interventions. The resulting negative experiences can also undermine trust in clinical procedures and create barriers to timely care. Clinicians report challenges in balancing adequate cervical stabilization with minimizing pain, highlighting a critical gap in available tools. Therefore, there is a clear need for a safer and more comfortable tenaculum design that **reduces tissue trauma, improves the patient experience, and maintains the stability** required for effective and efficient clinical performance.



89%
of women report moderate-to-severe pain when a traditional tenaculum is used

18%
of women refuse IUDs solely due to fear of the tenaculum.

Mission Statement

Advance women's health by enabling atraumatic cervical stabilization that preserves procedural control while minimizing patient pain, bleeding, and anxiety.

Design Inputs

User Need	Metric
Ease of Use	User Feedback
Patient Comfort	Patient Feedback (VAS Scale)
Cost	Cost per device ($)
Sterilization	Number of Sterilization Cycles Tolerated; Compatibility with Standard Methods (Autoclave/ETO)
Ergonomic Handling	Grip Force (N); Hand Soreness; Device Weight (g)
Durability/Longevity	Number of Sterilization Cycles Lasted; Years Used
Stabilization	Stability during Procedure; User Feedback

Table 1: User needs and their corresponding metrics for the reimagined tenaculum, highlighting key considerations such as ease of use, patient comfort, sterilization tolerance, ergonomic handling, durability, and procedural stability to guide engineering specifications.

Device Concept and Design

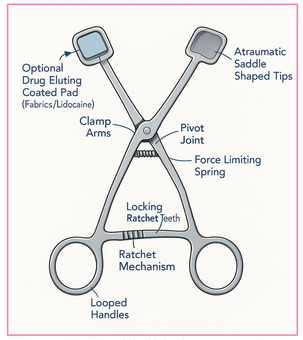


Figure 1: Detailed device concept rendering of the Reimagined Tenaculum

- Atraumatic Saddle-Shaped Tips
  - Broad, rounded geometry distributes pressure and minimizes tissue puncture or tearing.
- Drug-Eluting Coated Pad (Lidocaine)
  - Removable or integrated pads that release topical anesthetic to reduce patient discomfort.
- Clamp Arms
  - Smooth opening and closing of the device.
- Force-Limiting Spring
- Interlocking teeth
  - Controlled incremental closure of the tenaculum.
- Looped Handles

Technical Models

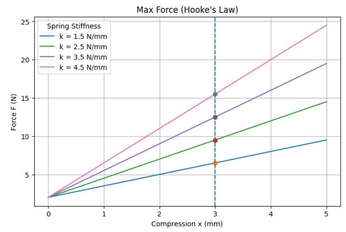


Figure 2: This model uses Hooke's Law to cap clamp force below 9–10 N, preventing excessive pressure on cervical tissue and ensuring consistent, safe traction.

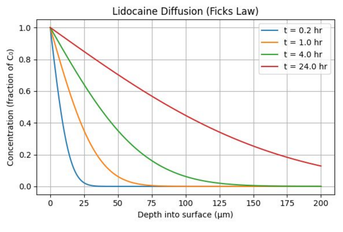


Figure 3: Fick's Second Law predicts how lidocaine diffuses from the pad into tissue over time, ensuring controlled anesthetic release for improved patient comfort.

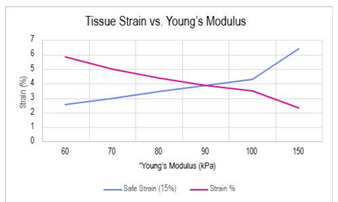


Figure 4: Using cervical Young's modulus, this model predicts tissue strain under load to verify that deformation stays below the safe 15% threshold.

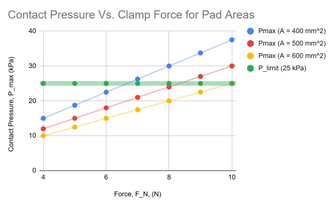


Figure 5: This model calculates average and peak pressures on the cervix to ensure pad forces remain below the 25–30 kPa pain threshold while maintaining stable grip.

Product Architecture

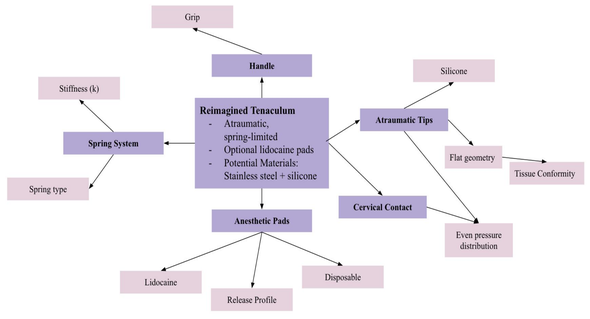


Figure 6: Simplified product architecture diagram for the Reimagined Tenaculum.

Link to fully detailed product architecture map.

Final Product Specifications

Specification	Target Value	Acceptable Range/Limit
Clamping Force	1.5 N	1.5-4.5 N
Contact Pressure	≤ 25 kPa	≤ 30 kPa
Tissue Strain	≤ 15%	≤ 20%
Tip Contact Area	~600 mm^2	550 - 650 mm^2
Handle Actuation Force	~10 N	≤15 N
Sterilization Durability	≥200 Autoclave Cycles	≥200 Autoclave Cycles

Table 2: Reimagined Tenaculum product specifications with target device parameters that meet medical device and FDA standards

Costs

Description	Annual Cost	Unit Cost
Direct Materials	$88,613	$21.47
Labor	$150,000	$30
Manufacturing Overhead	$34,000	$6.80

Cost Breakdown

Table 3: Simplified manufacturing and labor costs per year and per unit, assuming **5000 units per year**. The total cost per device to make a 20% profit is **$73**.

Project Planning

Gantt Chart

DT 1	Initial Setup & Early Project Documentation
DT 2	Project Selection & Planning Documentation
DT 3	Ideation & Needs Assessment Documentation
DT 4	Concept Development Documentation
DT 5	Concept Evaluation & Selection Documentation
DT 6	Technical Refinement Documentation
DT 7	Regulatory & Specifications Documentation
DT 8	Final Comprehensive Documentation

Table 4: Project documentation timeline

Future Directions

1. Finalize material selection and submit orders.
2. Refine models and test critical design parameters.
3. Develop first-generation physical prototypes and begin assembly.

Acknowledgements & References

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References