Team 6 - Salura Health - Reimagined Tenaculum

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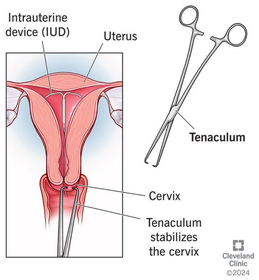
Clinical need

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.

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

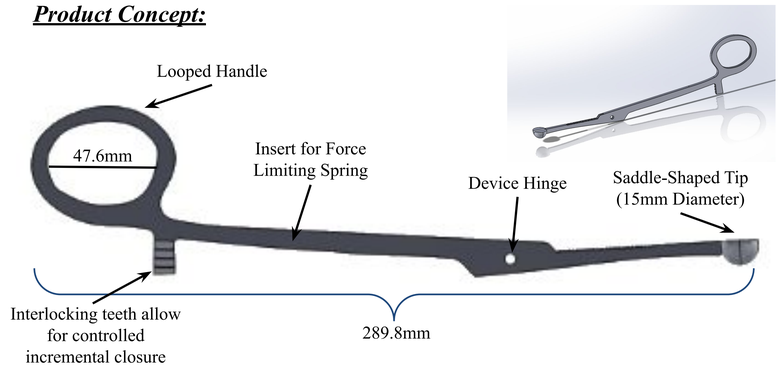
Table 1: Reimagined Tenaculum product specifications with target device parameters that meet medical device and FDA standards

Key Takeaways

- Atraumatic design reduces pain and bleeding vs. traditional tenacula
- Prototype demonstrates safe force limits but requires improved retention
- Compatible with existing clinical workflow

Product Concept and Design

Product Concept:



Virtual and Physical Prototyping

Technical Models

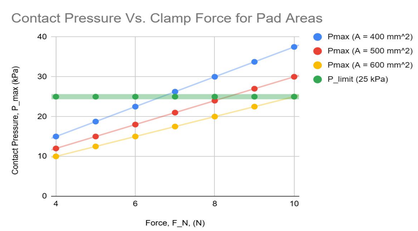


Figure 1: This model calculates average and peak pressures on the cervix to ensure pad forces remain below the 25–30 kPa pain threshold while maintaining stable grip.

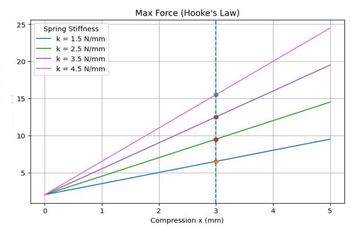


Figure 2: This model uses Hooke's Law to cap clamp force below 9–10 N, preventing excessive pressure on cervical tissue and ensuring consistent, safe traction.

Physical Testing

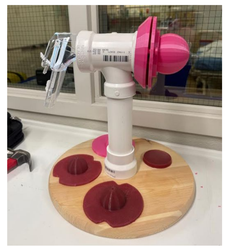


Figure 3: Image of cervix model used to test placement, retention, stability, and tissue interaction for final prototype.

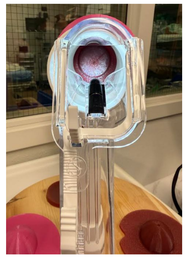


Figure 4: Image of cervix model from user perspective.

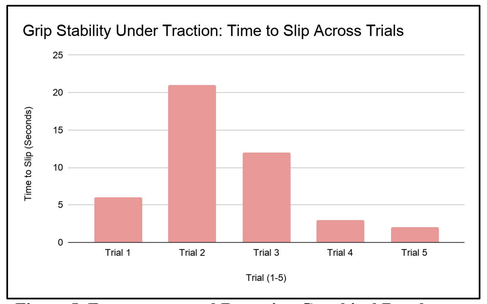


Figure 5. Engagement and Retention Graphical Results: Time to slip (seconds) across the five trials, which illustrates the variability and overall short duration of grip retention under the simulated traction testing.

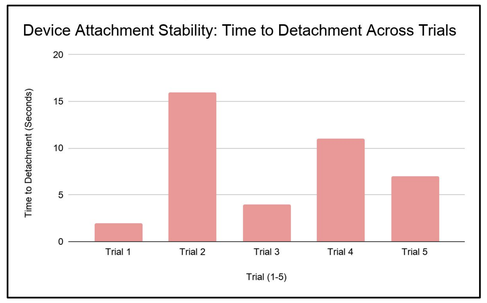


Figure 6. Stability Results: Time to complete detachment (seconds) across five trials, demonstrating the inability of the prototype to sustain a stable grip over time.

Physical Prototyping Cont.

Trial	Temporary Indentation Observed	No Tearing Observed	No Puncture Observed	No Permanent Deformation Observed
1				
2				
3				Left a small indent in the NE corner of the cervix, about 1mm in length.
4				
5				

Table 2. Tissue Interaction Results: Observations of deformation, tearing, puncture, and permanent damage to the silicone cervix across repeated applications. Green boxes indicate no trauma, while red indicates occurrence of trauma.

Costs

Cost Category	Cost per Unit	Details
Direct Materials	~$2.40-$4.80	Stainless Steel, Hinges/Pins
Direct Labor	~$1.20-$2.40	Forging, Heat Treatment, Polishing, Machining
Manufacturing Overhead	~1.80-$3.60	Factory Rent, Utility Costs, Maintenance

Cost Breakdown

Table 3. Estimates for mass production of tenaculum based on current market options

Regulatory Pathway

Class II Medical Device → FDA Oversight by CDRH → 510(k) Premarket Notification using Predicate Tenaculua

Future Directions

Refine models and test critical design parameters. → Expanded Testing and Design Refinement → Preclinical Validation and Safety Assessment → Regulatory Submission (510(k)) → Manufacturing Scale-Up → Clinical Adoption and Market Launch

Acknowledgements & References

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References