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UTERRA™ BY ILLUMIGYN: DEVELOPING A UTERINE MANIPULATOR FOR LAPAROSCOPIC HYSTERECTOMIES WITH AN ILLUMINATED COLPOTOMY CUP

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ILLUMIGYN
PRECISION IN A NEW LIGHT

BACKGROUND

A **laparoscopic hysterectomy** is a minimally invasive surgical procedure where the uterus is removed using abdominal incisions and specialized instruments, including a uterine manipulator.

A **uterine manipulator** is inserted transvaginally during the procedure and it allows the surgeon to reposition the uterus to provide a clear operative field to dissect ligaments, seal blood vessels, and mobilize surrounding vessels.

Clinical Problem: Surgeons face a trade-off with illumination and shaft ergonomics that comply with the female pelvic anatomy. Current devices only provide one or the other.

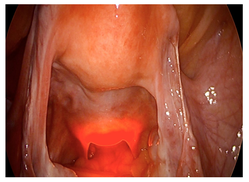


Figure 1. Image of the uterus during a laparoscopic hysterectomy with cervix illuminated.

Figure 2. Cross sectional, sagittal view of the female pelvic anatomy.

The colpotomy cup of the uterine manipulator presses against the cervico-vaginal junction, an area that the surgeon must dissect. Without a light, this junction is difficult to find.

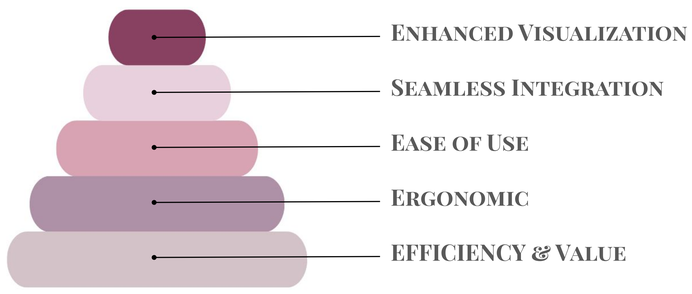
As shown in figure 2, the vagina and the uterus are not straight, creating the need for an S-shaped device.

MISSION STATEMENT

Our mission at Illumigyn is to enhance surgical **precision** and **safety** in women's health through **ergonomic**, **illuminated** technology designed **by women, for women**.

FINAL PRODUCT SPECIFICATIONS

Customer Needs



Resulting Technical Specifications

Illumination System incl. illuminated colpotomy cup	> 500 lux and < 41°C for patient safety
Power source included	External 12V battery powered
Mimics currently approved devices	13" body and 4" handle 180° uterine movement
Ergonomic, comfortable handle designed for long procedures	Fits glove sizes S-L
Low cost	Priced competitively at $320 USD

Scan QR code for detailed cost & ROI analysis ➡

PROTOTYPE

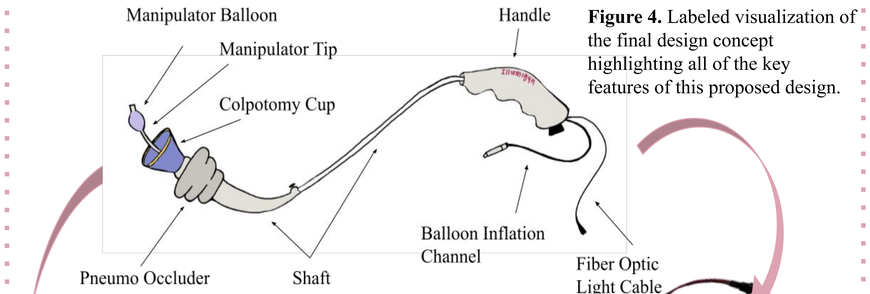


Figure 4. Labeled visualization of the final design concept highlighting all of the key features of this proposed design.

Figure 5. Detailed view of the illuminated colpotomy cup, pneumo occluder, and the manipulator tip.

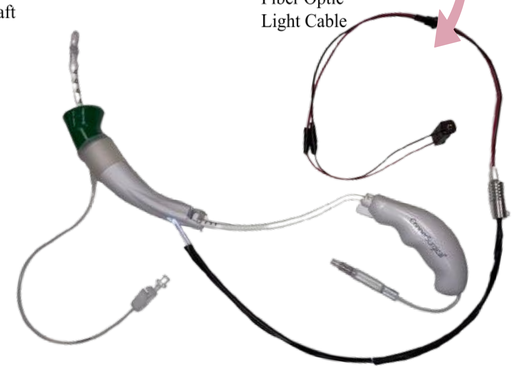


Figure 6. Final working prototype. Including fiber optic light cable and battery source.

FINAL TECHNICAL MODEL

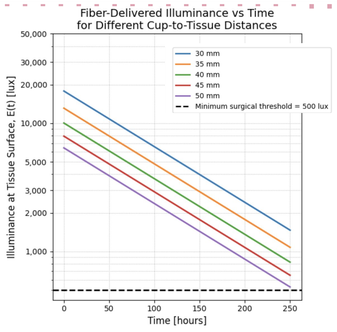


Figure 7: Model of illuminance vs time for different cup to tissue distances.

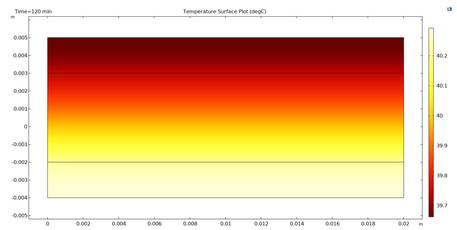


Figure 8: Temperature at 2 hours from light source, to cervical cup, through cervical tissue.

REGULATORY REQUIREMENTS

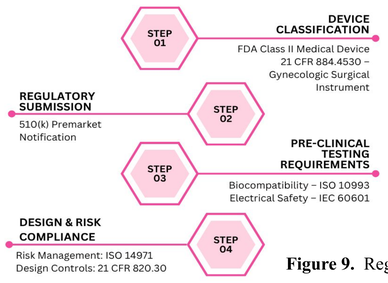


Figure 9. Regulatory Pathway.

- Class II medical device.
- 510(k) submission
  - Demonstrate substantial equivalence to existing manipulators
- Evaluating biocompatibility under ISO standards.

VERIFICATION RESULTS

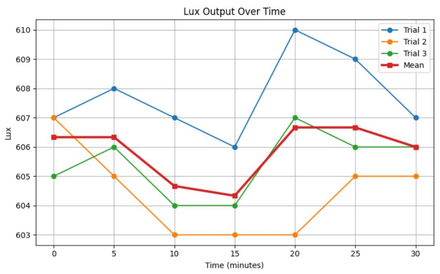


Figure 10: The lux output over time. One way ANOVA performed (p = 0.139)

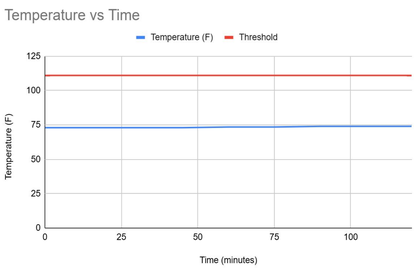
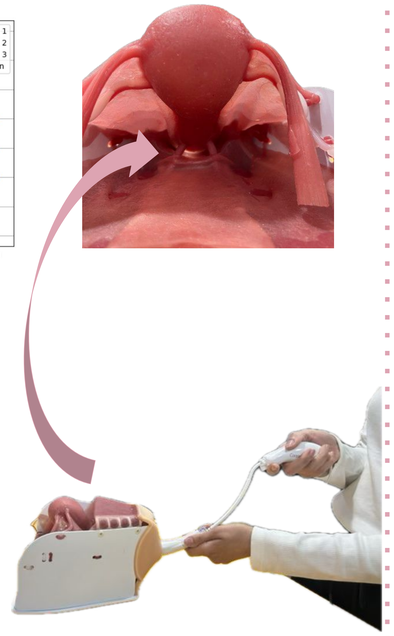


Figure 11: The temperature over time (2 hours)



DESIGN STATUS & FUTURE STEPS

- DT1: Final Technical Models
- DT2: SOP's, QSR, Developing Prototype
- DT3: Training
- DT4: Regulatory & Clinical Trials
- DT5: Recall Analysis & Risk
- DT6: Manufacturing Assessment
- DT7: Final Prototype & Verification
- DT8: Final Documents ← *Illumigyn Current Status*

Detailed Timeline/ Gantt Chart

Design Tasks: Includes finalizing the materials and the prototype.

Future Work: Construct ergonomic handle for all surgeon hand sizes.

Future Design: Future Designs include ergonomic design making devices suitable for the female hands.

REFERENCES & ACKNOWLEDGEMENTS

References

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