Device to Standardize Laparoscopic Surgery

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Laporoscopic Surgery

Laparoscopic Surgery

- Minimally invasive surgery performed on the abdomen or pelvis [1]
- Most common technique utilizes a thin, spring-loaded Veress Needle

Problem: Veress technique is a 'blind approach'

1. Limited visualization during Veress Needle insertion
2. Surgeons act blindly and rely only on sense of touch and judgement [2]
3. High potential to overshoot needle insertion and puncture bowels which leading to sepsis or death [3]

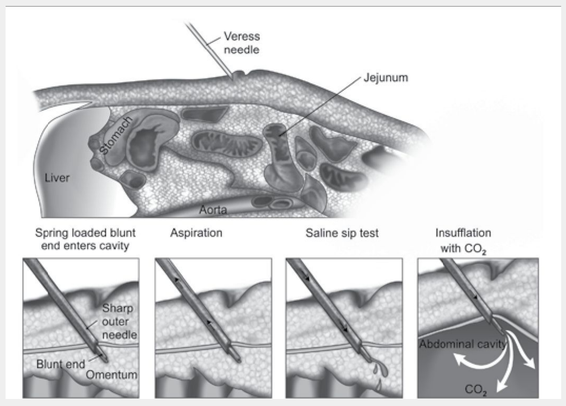


Figure 1. *Image detailing limited visualization of Veress Needle [4]*

Design Criteria

Safety: Reduce tissue trauma and avoid bowel puncturing
Verification/Detection: Locate needle position relative to body
Ease of Use: Ensure compatibility with OR workflow
Ergonomic Features: Ensure compatibility with CO2 insufflation tool and other surgical devices

Standards

Our innovative surgical Stainless Steel Veress needle would need to meet FDA regulation 21 CFR 884.1730, ISO 13485:2016, ISO 11607:2019, ISO 11135:2014, and ASTM F1744-96(2016). The needle is in contact with abdominal skin and wall tissue for <24 hours so the device must also meet: ISO 10993-5: 2009, ISO 10993-10: 2010, ISO 10993-11: 2006, and USP 39 <85>-Bacterial endotoxin test.

Prototype

Overall Design

- Design a pH-sensing Veress Needle to detect changes in tissue levels
- Basing our prototype on an article of a smart-sensing biopsy needle [5]

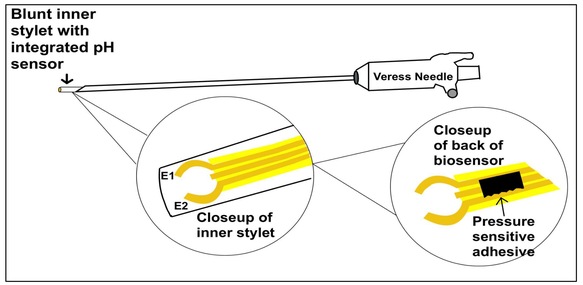


Figure 2. *Overall Schematic of pH Sensing Electrodes Adhered to Veress Needle*

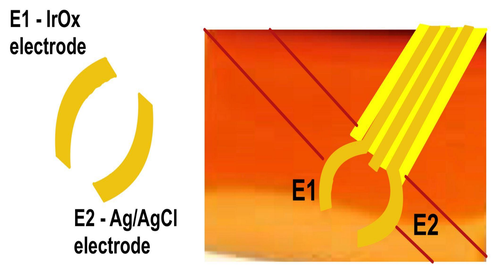


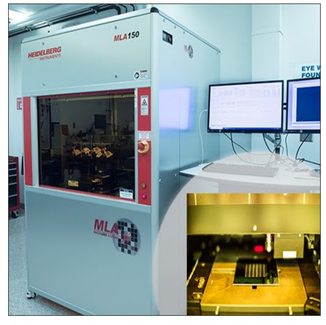
Figure 3*. Schematic of Electrode Design*

Electrode Design

- Designed 2D schematics of electrodes
- pH sensing electrode 1 layered in IrOx with Ag/AgCl reference electrode
- Utilize MRL's photolithography lab to fabricate electrodes

Electrode Fabrication

- Designed CAD electrode pattern for photolithography
- Photolithography transfers electrode pattern to flexible polyimide film using diode lasers



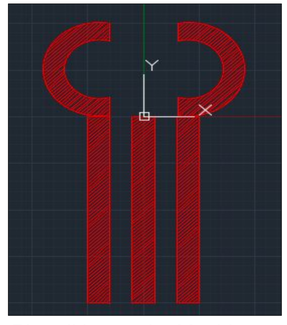


Figure 4 (left). *UIUC's Heidelberg Photolithography Machine*
Figure 5 (right). *AutoCAD Electrode Pattern*

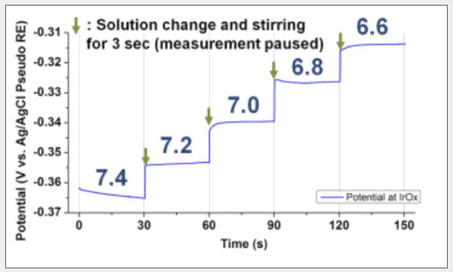
Figure 6 (left). *Fusion360 Left Electrode Pattern*
Figure 7 (right). *Finished 3D Printing Design*

Demonstration Prototype

- Converted CAD in Fusion 360 to 3D print
- Aid in visualization and further development of electrical components

Testing

1. *Calibrate and test accuracy of pH sensor against known solutions.*



2. *Test needle mechanics at the Jump Simulation Center.*
3. *First test on biological substance: cadaver lab with Director of Anatomy at Carle College of Medicine.*

Future Directions

Week 1/2: Continue to train with Dr. Wang and Dr. Sardela in the Lithography Lab at the MRL. Within the next two weeks, we hope to complete the fabrication process and have a pH sensing electrode.

Week 3: Complete five-point calibration method and reach accuracy level used at the IBRL at the University of Illinois.

Week 4: Begin prototype testing. Stages of testing described above.

Acknowledgements

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References

[1] Giorgi, Anna. "Laparoscopy: Purpose, Preparation, Procedure, and Recovery."

[2] Spiller, M., *et al.* Surgeons' requirements for a surgical support system to improve laparoscopic access.

[3] Ulker, Kahraman, et al. "Large Bowel Injuries during Gynecological Laparoscopy."

[4] Rai, M. Comparison between different entry techniques in performing pneumoperitoneum in laparoscopic gynecological surgery.

[5] Park, Jaeho, et al. "Biopsy Needle Integrated with Multi-Modal Physical/Chemical Sensor Array."