

LaproClear

A Laparoscopic Lens Cleaning Device

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CLINICAL PROBLEM

15 million laparoscopic (minimally invasive) surgeries are performed per year.



Figure 1: Laparo scopic Surgery. The Surgeon relies on a laparoscope (stick-shaped camera) to see during the operation.

The scope lens frequently becomes obscured with bodily fluids, causing:



longer operation time



higher hospital costs



workflow interruption

REGULATION & PATENTS

Regulatory Pathway: LaproClear qualifies as a Class Il Device, thus it will require 510(k) premarket notification.

Patent Potential: This is a useful, novel, and nonobvious design with no risk of patent infringement Current patented products include:

- · Clearify: an external surfactant cleaner requiring scope removal
- · ClickClean: a clear protective layer that shifts once smudaed
- Floshield: a device that pumps CO₂ in front of the lens to redirect smoke, fog, or other small particles

DEVICE DESIGN

Design Objectives:

- 1. Effectively cleans lens without removing the laparoscope
- 2. Fits within the 12mm inner diameter of trocar
- Biocompatible: is made of safe materials
- 4. User-friendly controls: can be operated easily with the hand already holding the laparoscope

Design hidden due to pending paten application

DEVICE FUNCTIONALITY

In Vitro: Butter and steam to simulate surgical conditions on large-scale model

· Demonstrated full efficacy in as little as 1-2 wipes

In Vitro: Blood efficacy testing with LaproClear device



Figure 5: Blood Efficacy Testing Images Camera View.

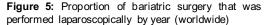
a) No wiper b) Wiper attached c) Dipped in blood d) Wiped once e) Wiped 4 times

- Device able to clear lens when obscured by non-coagulated blood in 4 wipes
- · Device fails after blood coagulates on laparoscope or the device

- · Porcine laparoscopic surgery
- Device completely cleared the lens after ~15 wipes

MARKET & COST

Market: Laparoscopic surgeries are more common



Estimated manufacturing cost: \$8.60 per device

- Sale price estimated to be in the range of \$30-50
- Cheaper than competitor products, which are \$80-
- Insignificant cost relative to total cost of operation

Reimbursement: this device will not be taken home or repeatedly used, thus it cannot be reimbursed by Medicare or Medicaid.

FUTURE WORK

Biocompatibility

- · Determine sanitizing requirements
- Find better biocompatible and anticoagulant materials
- · Determine ideal wire material

More in vivo testina

- Quantitatively measure cleaning efficacy
- Clinical testing

Bringing to Market

- File patent application
- FDA approval
- · Design alterations for large-scale manufacturing

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