



MAINTAIN ALL-IMPORTANT VISIBILITY DURING LAPAROSCOPIC SURGERY

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OBJECTIVE

Surgeons rely completely on the scope for visualization on all minimally invasive procedures. That all-important view is repeatedly impaired during surgery when blood, smoke and water vapor obscure the lens. The surgeon cannot safely proceed, so surgery must be paused while the scope is removed, the optics are cleaned, and the scope is reinserted into the trocar. Not only is this a major frustration for surgeons, whose focus is repeatedly interrupted, but it is also quite time-consuming. Each removal disturbs the flow of a surgical procedure and adds time for cleaning, as well as for the surgeon to refocus. 1 The objective of Medeon Biodesign is to permit in situ lens cleaning during laparoscopic surgery to maintain visualization and allow procedures to continue uninterrupted.

SOLUTION

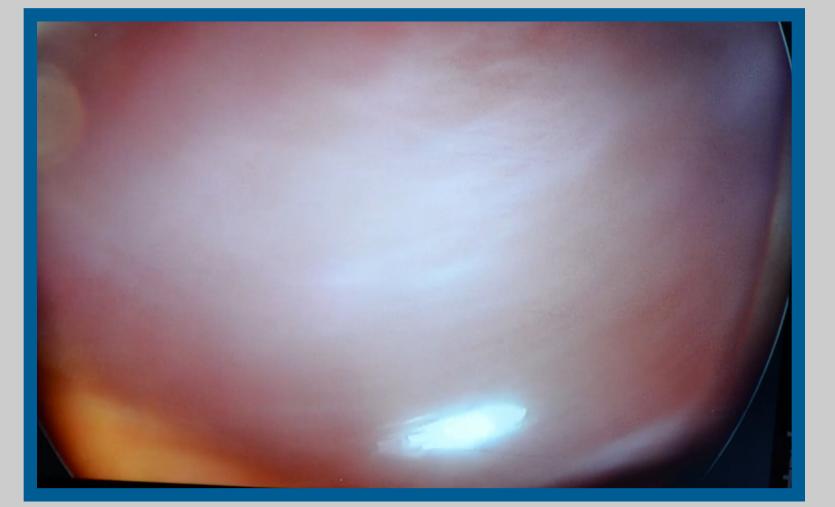
ClickClean is a disposable device intended to maintain the laparoscopic view during surgery. It is comprised of a sheath, a trigger box, and a transparent, biocompatible film that slides in front of the laparoscopic tip. The scope's view through this film is perfectly clear. When it is soiled, the surgeon clicks the trigger, sliding a fresh length of film into place. This takes seconds, and the scope is never removed. The surgeon maintains a clear, unobstructed view without interruption or distraction.

DATA

A 10mm ClickClean device is now in clinical use, and a 5mm version has recently undergone animal study. Initially, 30 10mm ClickClean clinical cases were performed by 12 different surgeons. The cases were 27 laparoscopic cholecystectomies (including 1 with cholecystostomy tube placement and another with diagnostic laparoscopy) and 2 gastric bypass procedures. During surgery, lenses were obscured by smoke, fog, fat, and blood. Surgeons averaged 3.7 ClickClean cleanings per case with 2.8 clicks per cleaning. The surgeons said the learning curve was one case. All surgeons said ClickClean was valuable for reducing scope removals, stating the device avoided > 90 % of scope removals during surgery. Surgeons commented that ClickClean "saved time," "reduced frustration by clearing away smoke, splatter, and blood;" "Perfect for difficult dissection; and "The picture is perfect. Never need to defog the scope." In an animal lab study of the 5mm ClickClean device this past November, researchers evaluated functional performance and safety of ClickClean based on laparoscopic view quality, organ/tissue touch, blood touch, usability and safety. ClickClean was nearly always able to restore the laparoscopic view in one click, regardless of the source or substance obscuring the lens. Multiple clicks were only needed in challenging conditions, such as irrigation and blood dip.

CONCLUSION

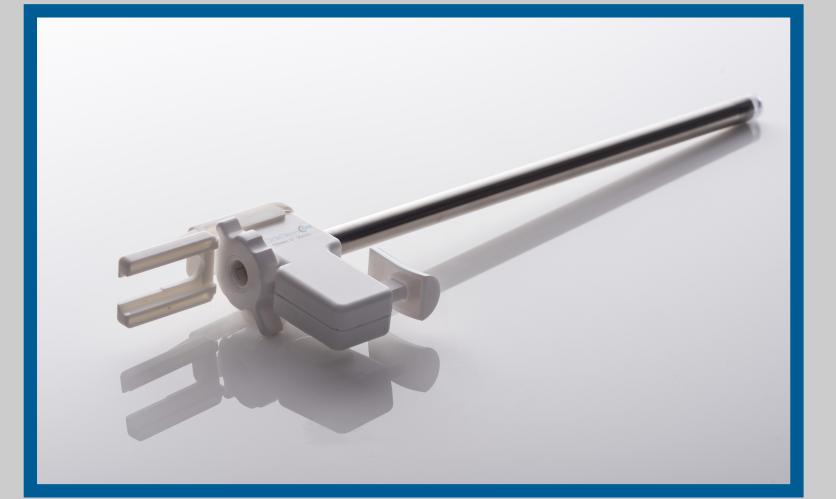
ClickClean has proven its efficacy for in situ cleaning of the laparoscopic lens in all conditions, alleviating surgeons' number one frustration. This new device allow surgery to continue uninterrupted with clean, clear, continuous visualization, making it an exciting advance for laparoscopic surgeons.

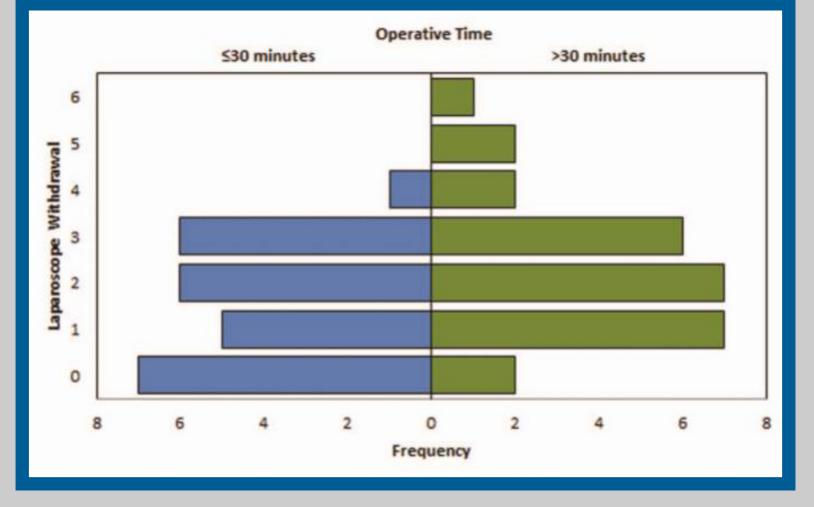


Before Cleaning

After Cleaning







Performance of ClickClean Device	Likert Scale (7= Completely satisfied; 1 = Completely dissatisfied)
Overall clarity of image	6.8
Ability to maintain a clean and clear image from smudging	6.7
Reduction of scope removals due to smudging/fogging during the procedure	6.9
Value of the reduction in scope removals	6.8

CLICKCLEAN™ Laparoscope Cleaning Device

83% cases required scope withdrawal for cleaning¹

Surgeon's Satisfaction of Device Performance in Likert Scale