

# Safety and performance evaluation of the AutoLap system - a feasibility study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal signs and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39368

### Source

ToetsingOnline

### Brief title

Safety and performance of the AutoLap system

### Condition

- Gastrointestinal signs and symptoms
- Gastrointestinal therapeutic procedures

### Synonym

cholecystolithiasis, colectomie, gallstones, hernia repair, Nissen fundoplication

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Medical Surgical technologies ltd

**Source(s) of monetary or material Support:** MST Medical Surgical Technologies;Ltd

## Intervention

**Keyword:** AutoLap, Endoscope, Steering

## Outcome measures

### Primary outcome

Performance Evaluation:

- The ability of the AutoLap system to successfully move the laparoscope to the surgeon's desired position. Success is defined as bringing the laparoscope to the desired position in at least 85% of the required movements.

Parameters that relate to the performance of an endoscope during endoscopic surgery

- 1) System set-up time recording
- 2) Average total procedure time recording
- 3) Number of times that the laparoscope was removed for cleaning.
- 4) Usability - the AutoLap system usability in laparoscopic procedures will be assessed by a questionnaire.

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### Secondary outcome

Safety Evaluation:

- 1) No conversion to open surgery from laparoscopic surgery due to using the AutoLap system.

2) No AutoLap system related operative complications that require further clinical intervention.

## Study description

### Background summary

During Laparoscopic treatment of surgical diseases an assistant is typically required to hold and position the camera according to the commands of the surgeon.

The assistant's ability to anticipate the next camera placement is not always optimal, and communication problems occasionally occur. Holding the camera may also be exhausting in long surgical procedures, leading to fatigue and, potentially, unsteady images. Furthermore, depth perception may be impaired when the surgeon is not directing the camera.

MST has developed the AutoLap system, an active laparoscope positioner. The AutoLap system is designed to hold and position the laparoscope during laparoscopic surgery. When the camera is in position, the AutoLap system holds the laparoscope steady as with any laparoscopic positioner. To maneuver the laparoscope to the desired position, the surgeon presses a single button, which is affixed to his hand or to the surgical instrument.

### Study objective

The main objectives of this study are to evaluate the safety and performance of the AutoLap system in the following laparoscopic procedures: hernia repair, cholecystectomy, right colectomy, Nissen fundoplication and sigmoidresection. The AutoLap system will be evaluated in Smart Joystick mode.

### Study design

Prospective, single arm (non-randomized), multicenter study involving up to 40 subjects in The Netherlands, Israel and Italy, who are planned for the following laparoscopic procedures: hernia repair, cholecystectomy, right colectomy, Nissen fundoplication and sigmoidresection.

### Intervention

Laparoscopic cholecystectomy, hernia repair, right colectomy, Nissen fundoplication and sigmoidresection conform national guidelines

### Study burden and risks

Minimal/theoretical: damage to internal organs due to unexpected or rude movements of the endoscope  
potential benefits:

The AutoLap system is designed to enable full control of the surgeon on the desired field of view and of the surgical procedure, thus eliminating the limitation of dis-coordination between the surgeon and the camera holder, possibly providing an image which is more stable, and the ability to maximize the efficacy of the operation room personnel.

## Contacts

### Public

Medical Surgical technologies ltd

kochav yokneam building 5  
yokneam illit 20692  
IL

### Scientific

Medical Surgical technologies ltd

kochav yokneam building 5  
yokneam illit 20692  
IL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients between 18 and 85 years of age who were scheduled for elective laparoscopic procedures: cholecystectomy, hernia repair, right colectomy, Nissen fundoplication and

sigmoid resection

## Exclusion criteria

1. Previous upper abdominal surgery and contraindications to Pneumoperitoneum.
2. Pregnancy.
3. Obesity (BMI >35 Kg/m<sup>2</sup>).
4. Generalized peritonitis.
5. Septic shock from cholangitis

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL  
Recruitment status: Recruitment stopped

Start date (anticipated): 31-01-2014

Enrollment: 25

Type: Actual

### Medical products/devices used

Generic name: AutoLap System

Registration: No

## Ethics review

Approved WMO

Date: 18-12-2012

Application type: First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL41349.100.12