

LENS (ClickClean™)

Laparoscope Lens Shield Device

Model: UL030/ UL330/ L030/ L032/ L042

Instructions for Use

Indication for Use

Laparoscope Lens Shield Device (LENS), a sterile, single-use and disposable laparoscopic accessory lens shield device, for various sizes of laparoscopes including standard and bariatric laparoscope, intended to maintain the intra-operative view of the surgical site during minimally invasive surgery by physically shielding the laparoscope lens from debris, grease, blood, and bodily fluids.

Warnings

LENS is a single-use, disposable device that is not intended to be reused. Any attempt to clean, re-sterilize and reuse the device may compromise its safety or effectiveness and may cause serious injury to a patient. Dispose properly and safely of all open products, used or unused, after the procedure is concluded.

Precautions

- Sterile technique should be used in opening the package. Do not use if the package is found opened or damaged.
- Care should be taken to avoid damage to the device's distal end (Cap), **especially when inserting the laparoscope into LENS**. Do not use if the cap is missing or damaged.
- Ensure that the LENS has been properly locked onto the shaft of the laparoscope. If LENS is not secured, its functionality may be compromised, depth of laparoscopic penetration may be adversely affected, and the LENS may be damaged.
- **DO NOT** use sterile water, anti-fogging gel or solution on LENS before or during surgery.
- Given its specific dimensions, LENS will accommodate a 10 mm laparoscope (outside diameter) and the LENS / Laparoscope Assembly must be used in combination with a 12 mm (inside diameter for UL030, UL330, L030, L032 and L042) laparoscopic trocar.
- Use prior to the last day of the month of expiration.
- There are no known adverse reactions to the materials used in this device. If a patient does react adversely, discontinue use.

Directions for Use

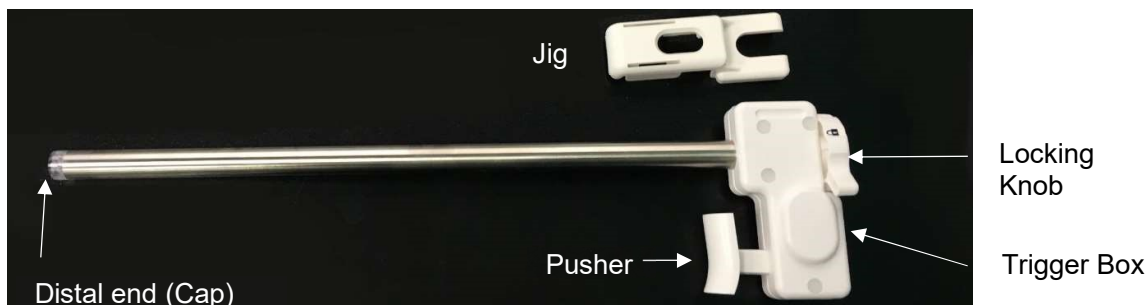
Caution: The following directions for use are provided for the set up and use of LENS. This device should be used only in concert with widely accepted good surgical practices, using sterile technique, and only by qualified technicians/ operating room personnel with appropriate training.

CONFIRM CONTENTS

The disposable LENS consists of the following:

One (1) LENS Main Device

One (1) Jig



Functional Structure of Laparoscope Lens Shield Device (LENS)


OPENING THE PACKAGE


Open the pouch at the chevron seal and remove the sterile contents. (Note: Contents of the pouch are sterile unless package is breached or damaged.) In opening the package, O.R. personnel should use sterile technique and proceed in compliance with their established institutional protocols.

SET UP

1. **Device Pretest:** Press the Pusher of LENS and confirm smooth sliding of film.

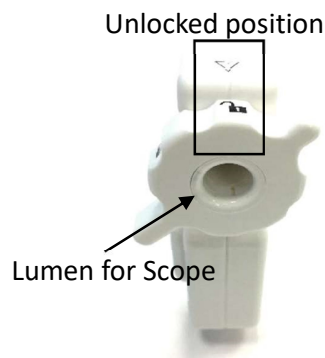
2. **Assemble LENS and Laparoscope:**

(1) **LENS Preparation:** Confirm the **Locking Knob** is in the unlocked position by aligning the Arrow Mark  on the top of the Trigger Box with the Unlock

Mark  on the Locking Knob before inserting the laparoscope into the Lumen for Scope.

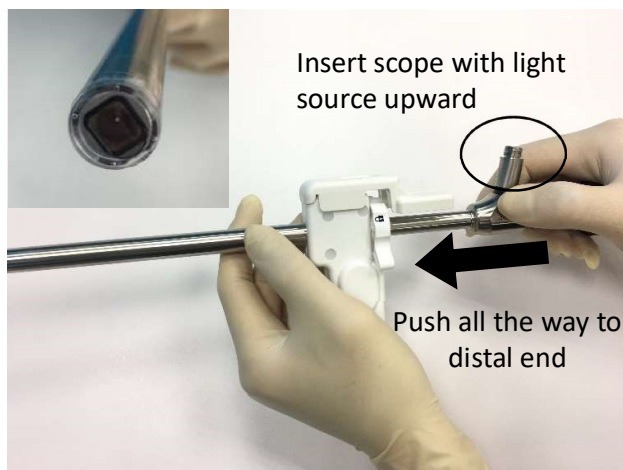
(2) **Assemble Jig onto LENS:** While holding the Trigger Box, press Jig down firmly onto the top of the Trigger Box

(3) **Assemble LENS onto Laparoscope:** While holding the LENS, **SLOWLY PUSH** the laparoscope, with the light source upwards, into the lumen of the Locking Knob, creating the LENS/ Laparoscope Assembly. The final position for the lens is against the distal end (Cap) of LENS.





Important:

- Ensure the light source adaptor slide in the Jig
- Do not use excessive force when inserting the laparoscope into the LENS, or “slam” the laparoscope into the back of LENS distal end (Cap).



- (4) **Check LENS / Laparoscope Assembly:** Check the image of laparoscope to ensure LENS is in place.

Important: Image quality needs to be checked first. Otherwise, LENS functionality may be compromised, depth of laparoscopic penetration may be adversely affected, and the LENS may be damaged.

3. **Tighten LENS / Laparoscope Assembly:**
Holding the LENS / Laparoscope Assembly and rotate the Locking Knob clockwise and align the Arrow Mark  with the Lock Mark  to lock LENS onto the laparoscope.



4. **Warm up LENS / Laparoscope Assembly by Standard Laparoscope Warmer**

If a laparoscope warmer is used, please ensure the length of the warmer is longer than 30cm. Heat the LENS / Laparoscope Assembly by the warmer for at least 5 minutes. Ensure the distal end of LENS / Laparoscope Assembly is fully covered by the warmer.

OPERATING THE DEVICE

1. Insert the LENS / Laparoscope Assembly through a trocar to acquire visualization of the surgical site as usual.

Caution: Do not use excessive force during insertion of the LENS / Laparoscope Assembly into the trocar.



2. Press the Pusher to clean the view.
ALWAYS ORIENT the trigger box of LENS DOWNWARD before restoring the laparoscope view during the normal course of surgery.
3. When the image is smeared by fluid or smoke, press the Pusher of LENS immediately to restore view during the procedure. More than one click may be needed in some cases to restore the view.

Important:

- Do not immerse the LENS/ Laparoscope Assembly into sterile water, anti-fogging

- gel, or solution during surgery.
- Do not wipe the distal end (Cap) of LENS by gauze or organ during surgery.
 - If blood or fluids infiltrated into the space between the distal end of LENS and laparoscope lens, discard the soiled LENS and use a new LENS.





Always keep the trigger box downward while triggering the device

SCOPE EXCHANGE

In the event that different laparoscopes may be needed during surgery, simply discard the unneeded LENS. Use another piece of LENS with proper diameter/length/direction of view for further procedure.

REMOVAL / DISASSEMBLY

1. At the conclusion of surgery, withdraw the LENS/ Laparoscope Assembly from the trocar.
2. Unlock the assembly by rotating the Locking Knob counterclockwise, aligning the Arrow Mark  with the Unlock Mark .



3. Slide the laparoscope out of LENS.

Important: Care should be taken not to inadvertently drop and damage the laparoscope once the assembly has been unlocked.

4. Dispose the used LENS.

Important: Used LENS should be treated as bio-hazardous waste, and its disposal should be completed in accordance with established institutional protocols

Storage Conditions

LENS should be stored under standard room environment.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician (or allied healthcare professionals, authorized by, or under the direction of, such physicians) who is trained in laparoscopic procedures.

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