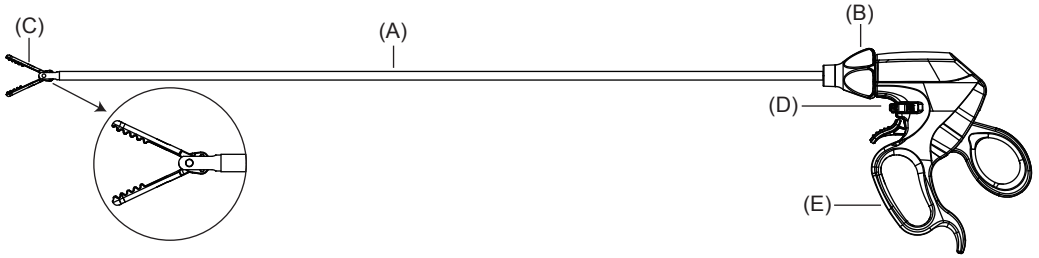
LAGIS® ENDOSCOPIC INSTRUMENTS - GRASPER

English

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

◆ DEVICE DESCRIPTION：

The LAGIS Endoscopic Instruments-Grasper is a single use device sterilized by ethylene oxide. It is composed of (A) an insulating shaft, (B) a rotation knob, (C) grasping forceps, (D) a ratchet, and (E) a handle. The 5 mm diameter insulating shaft is designed for use through appropriate size trocars. The rotation knob located on the handle rotates the insulating shaft 360 degrees in either direction for better maneuverability. With the ratchet handle, the grasping forceps are allowed to be locked in place. The grasping forceps are activated by compression and release of the ring of the handle.



◆ INDICATIONS/INTENDED PURPOSE：

1.The LAGIS Endoscopic Instruments-Grasper has applications in a variety of minimally invasive procedures to facilitate grasping and mobilization of tissue.

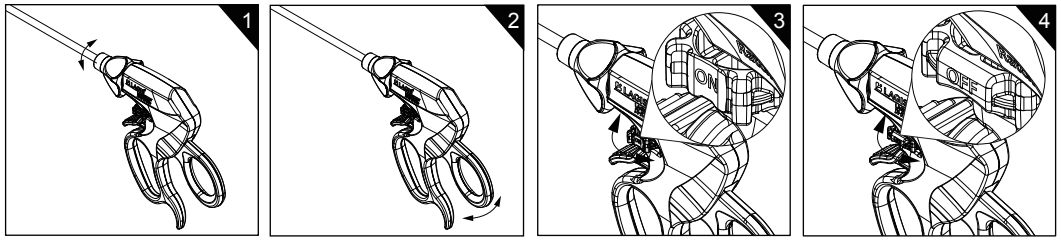
2.Patient target group: the LAGIS Endoscopic Instruments-Grasper is intended for adults who need minimally invasive procedures.

◆ CONTRAINDICATIONS：

The LAGIS Endoscopic Instruments-Grasper is not intended for contraceptive coagulation of fallopian tissue or for use when minimally invasive techniques are contraindicated.

◆ INSTRUCTIONS FOR USE：

Prior to use, inspect the contents of the packaging and the packaging itself to ensure the integrity is not compromised.



- Insert the LAGIS Endoscopic Instruments-Grasper through an appropriately sized trocar with the grasping forceps closed and direct it to the desired site.
  Note: The LAGIS Endoscopic Instruments-Grasper shall be introduced through the specific or larger size of trocar sleeve, otherwise the misuse may impair the performance of the trocar of the device itself.
- To rotate the grasping forceps, rotate the knob in either direction for the desired angle.(Illustration 1).
- Once the desired tissue is between the grasping forceps, compress the ring of the handle to facilitate clamping. (Illustration 2)To lock the grasping forceps in the desired condition, switch on the ratchet located on the handle.(Illustration 3)
- Switch off the ratchet to unlock the grasping forceps and release the ring of the handle to loosen the tissue from the grasping forceps.(Illustration 4)
- Retract the LAGIS Endoscopic Instruments-Grasper with the grasping forceps closed from the trocar.

◆ WARNINGS AND PRECAUTIONS：

- Do not use if the device or the sterile packaging is open or damaged, as this may cause an increase in the incidence of wound infections.
- If trocars or accessories from different manufacturers are used together in a procedure, verify compatibility prior to performing the procedure.
- Do not introduce or withdraw the LAGIS Endoscopic Instruments-Grasper with the forceps open through the trocar sleeve.
- This device is packaged and sterilized for single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocess, or resterilization may create contamination, infection, cross-infection, or even compromise the integrity of the device and lead to device failure which in turn may result in patient injury, illness or death.
- This device should be operated only by surgeons with adequate training and familiarity with surgical techniques. Consult medical literature for further information regarding techniques, hazards, contra-indications, and complications prior to performing the procedures.
- Return the device and packaging to the distributor or implement safe disposal handling by the healthcare professionals if the sterile packaging is damaged or unintentionally opened before use.
- The used device which comes into contact with bodily fluids should be considered as biomedical waste and safely disposed of by healthcare professionals in compliance with the national waste management regulation to prevent patients, users, and other persons from biological contamination or infection.
- Do not attempt to repair the device. The use of a defective device or a device that becomes defective during surgery may result in loose parts that could drop into the field of operation.
- In the event of malfunction of the device, changes in performance that they may affect safety, or even any serious incident, please report to the manufacturer, the competent authority of the Member State and the authorized representative immediately according to the contact information provided on the label or in this instructions for use.
- Improper assembly or operation of the device may result in tissue or organ injuries from mechanical damage to the patient or operator.

◆ ENVIRONMENTAL CONDITIONS FOR STORAGE：

Appropriate storage environment is a clean and dry area away from sunlight with a temperature range of 13~30°C (55.4~86°F).

◆ EXPLANATION OF SYMBOLS：

	Temperature limit		Caution	LATEX	Not made with natural rubber latex
STERILIZE	Do not resterilize		Manufacturer		Do not use if package is damaged and consult instructions for use
2	Do not re-use		Consult instructions for use or consult electronic instructions for use	STERILE EO	Sterilized using ethylene oxide
	Date of manufacture		Single sterile barrier system	MD	Medical device
℞ only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.				

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