

Warranty

This instrument is warranted for 1 year from the date of purchase for defects in materials and workmanship. Any defective instrument will be repaired or replaced at no charge, provided it is returned to the manufacturer sterile, prepaid, and marked with a valid Return Materials Authorization number (RMA). This warranty does not apply to misuse, abuse, or accidents during use. The manufacturer reserves the right to determine what constitutes defects in materials and workmanship. No other warranty is intended, expressed, or implied.

Christoudias

Double Grasper™

Instructions for Use

Item # DG530/25

READ AND UNDERSTAND ALL INFORMATION CAREFULLY BEFORE USE

In order to obtain optimum results, the following instructions should be followed. Otherwise, the instrument may not perform properly and/or injuries may result.

Caution: Federal law restricts this device to sale by or on the order of a physician.



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Christoudias Double Grasper (REF DG530)

INSTRUCTIONS FOR USE

CAUTION

USA federal law restricts the use of this Device to sale by, or on the order of, a physician.

INDICATIONS FOR USE

The indications for use for the Christoudias Double Grasper are to grasp and hold the tissues for approximation and in preparation for suturing or stapling in a variety of laparoscopic / endoscopic or open surgical procedures.

ATTENTION

- Read and understand all information contained in these Instructions for Use before using the Christoudias Double Grasper
- The Christoudias Double Grasper must be cleaned and sterilized prior to each procedure
- Care must be taken to avoid dropping or mishandling this instrument.

DESCRIPTION

A reusable surgical instrument designed to grasp and approximate tissue for stapling or suturing. This device may be used with a 5mm or larger trocar.

Non-sterile reusable surgical instrument

- DG530 Christoudias Double Grasper

CONTRAINDICATIONS

- Do not use Christoudias Double Grasper where hemostasis cannot be verified visually after application.
- Laparoscopic or open use of the Christoudias Double Grasper is contraindicated whenever surgical techniques or use of a grasping device are contraindicated for any reason

WARNING

- A thorough understanding of the principles and techniques involved in laser and electro-surgical procedures is essential to avoid shock and burn hazards to patients, operators, and to the instruments.
- Avoid any harsh materials that can scratch or mar the instrument surface.
- Store instruments at room temperature. Avoid prolonged elevated temperatures.
- Prior to use, clean and sterilize all reusable components according to the instructions

- As with any foreign material, the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.
- All surgical procedures should be performed only by persons having adequate training and familiarity with proper surgical techniques. Consult the medical literature relative to techniques, complications, and hazards prior to performance of any surgical procedure.

PRECAUTIONS

- When surgical instruments and accessories from different manufacturers are employed together in a procedure, verify their compatibility, and ensure that electrical isolation or grounding is not compromised.
- Endoscopic/laparoscopic procedures should be performed only by persons having adequate training and familiarity with laparoscopic techniques. Consult the medical literature relative to techniques, complications, and hazards prior to performing any laparoscopic procedures.

INSTRUMENT CLEANING AND STERILIZATION

Recommendation: Gloves should be worn when cleaning and handling contaminated instruments. All institutional guidelines for infection control should be followed. **Be sure to remove the flush port cap during cleaning and sterilization and to place back on before use. The flush port cap must be steam sterilized with the instrument.**

Cleaning the Instrument

1. Prepare the neutral-pH enzymatic detergent (safe for use with metal instruments) according to detergent manufacturer's recommendations. Do not use Glutaraldehyde.
2. Soak the entire device in neutral-pH enzymatic detergent for three (3) minutes. Flush the luer port with a minimum of 60cc of the neutral-pH enzymatic detergent and expel all air. Allow the unit to soak for a minimum of three (3) minutes.

STEAM STERILIZATION

Type of Autoclave Sterilization Method	Temperature of Gas Content	Minimum Exposure Time	Condition of Instrument
Gravity Displacement	270-272°F (132-133°C)	20 minutes	Wrapped
Pre-vacuumed	270-272°F (132-133°C)	4 minutes (10 minute dry time)	Wrapped

***Do not exceed 285°F/140**

3. Scrub the jaws and surrounding areas with a soft bristle brush and neutral-pH enzymatic detergent.
 4. Flush the luer port with a minimum of 60cc of water.
 5. Rinse the entire device under running water for a minimum of one minute.
 6. Inspect the device for blood and debris, repeat steps 1-5 as necessary.
 7. Instill 15cc of non-silicone instrument lubrication through the flush port.
 8. Tilt shaft back and forth and allow instrument to drain.
 9. **Do not gas sterilize the Christoudias Double Grasper.**
2. The depression on the right lever opens and closes the right silver jaw.
 3. **The flush port cap should be attached securely after sterilization to prevent loss of CO₂ during the procedure.**

INSTRUMENT INSPECTION AND WARRANTY

This instrument should be inspected and tested after each autoclave cycle and prior to each use. If the instrument fails to function as intended, contact Apollo Surgical Industries immediately for repair/replacement. Do not attempt to repair or modify this Device.

Instrument warranty is void if service / repair is not performed by an authorized Apollo Surgical Industries Service Representative. This warranty covers defects in materials and workmanship for one (1) year from date of purchase. No other warranties, expressed or implied, are covered by this warranty.

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US Patent: 5,403,332

INSTRUMENT DIRECTIONS FOR USE

1. The dimple on the left "gold" lever opens and closes the left gold jaw.