

## Instructions for Use Go Up

### **AMERICAN INSTRUMENTS EIRELI - EPP - CNPJ: 06.981.319/0001-21**

Avenue 53, 1227 – Jardim Kennedy – Zip Code: 13501-530 - Rio Claro/SP - Technical Resp.:

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Aiming at practicality and ease of access to the information contained in the Instructions for Use of our products, American Instruments in accordance with IN nº 4/2012 established by ANVISA, makes the documents available for download on the website: [http://www.americaninstruments.com.br/instrucao\\_uso](http://www.americaninstruments.com.br/instrucao_uso)

ANVISA Registration No. 80251140063 - Revision 00

### **PRODUCT FEATURES AND TECHNICAL SPECIFICATIONS**

**Technical Name:** Retractor

**Business Name:** Go Up

#### **Raw Material:**

Go Up Introducer: Stainless Steel (ASTM F899) + Polycarbonate (PC) (ASTM 1855)

Tube: Polypropylene (PP) (ASTM1855)

Suspension Strap: Polyacetal (POM) (ASTM 1855)

Clips: Polypropylene (PP) (ASTM 1855)

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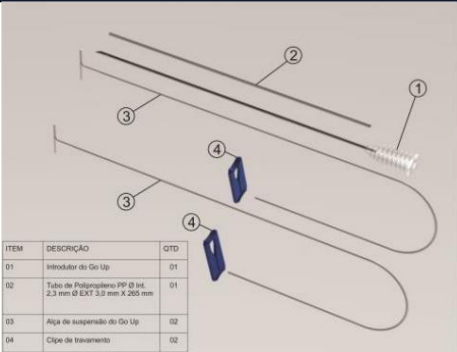
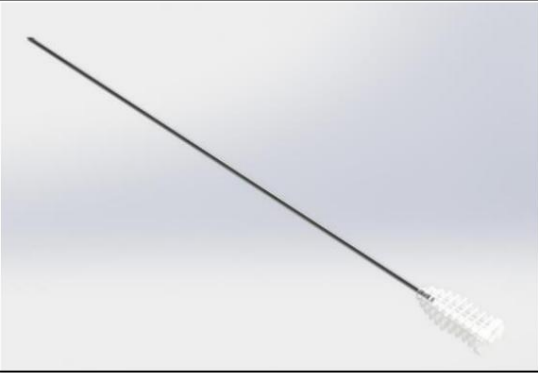

## Instructions for Use Go Up

**Shelf life:** 2 years after the date of manufacture

**Sterile Product - Disposable Product** - Sterilized by Ethylene Oxide - ETO

### IDENTIFICATION OF COMMERCIAL MODELS / COMPOSITION:

Go UP commercial model available for sale, as per the following table:

Reference	Image	Item/Part															
AI7222	 <table border="1" data-bbox="485 972 673 1084"> <thead> <tr> <th>ITEM</th> <th>DESCRIÇÃO</th> <th>QTD</th> </tr> </thead> <tbody> <tr> <td>01</td> <td>Introduzidor do Go Up</td> <td>01</td> </tr> <tr> <td>02</td> <td>Tubo de Polipropileno PP Ø Int. 2,3 mm Ø EXT 3,0 mm X 265 mm</td> <td>01</td> </tr> <tr> <td>03</td> <td>Alça de suspensão do Go Up</td> <td>02</td> </tr> <tr> <td>04</td> <td>Clipes de travamento</td> <td>02</td> </tr> </tbody> </table>	ITEM	DESCRIÇÃO	QTD	01	Introduzidor do Go Up	01	02	Tubo de Polipropileno PP Ø Int. 2,3 mm Ø EXT 3,0 mm X 265 mm	01	03	Alça de suspensão do Go Up	02	04	Clipes de travamento	02	<p>1. Go Up Introducer 2. Tube 3. Suspension Strap 4. Locking Clips</p>
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01	Introduzidor do Go Up	01															
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S-GOU001		Go Up Introducer															
S-GOU002		Go Suspension Strap Up															

### Instructions for Use Go Up

S-GOU003		Go Locking Clips Up
5601		Protection tube of the Go Up Introducer

## PRODUCT PRESENTATION FORM

The product is sold in individual packaging positioned in a display and inserted in pouch, manufactured with tyvek paper and film Polyester/Polypropylene laminate 150 x 370mm, which allows opening aseptic without tears in the film and with less release of fibers (packaging primary).

The pouch type packaging is packaged in an outer packaging of cardboard 110 x 150 x 375mm with 10 units.

The label also contains the following information: Instructions for Use available at [http://www.americaninstruments.com.br/instrucao\\_uso](http://www.americaninstruments.com.br/instrucao_uso). Reg. ANVISA: 80251140063 - Revision: 00. To obtain the printed version , contact: Phone: +55 19 3531-5116 - [info@americaninstruments.com.br](mailto:info@americaninstruments.com.br).

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We warn that it is necessary to observe the correlation between the version of the Instruction of Use available on the website, or printed, with the version indicated on the label of the product.

### LABELING TEMPLATE

Coated Label 100 x 80 mm



### INDICATION AND PURPOSE

The device consists of a disposable tissue retraction system which allows the surgeon to create operative space in the cavity abdominal during videolaparoscopic surgeries, through fixation and specimen exposure. Used percutaneously, there is no need of incisions.

### WORKING PRINCIPLE/ MECHANISM OF ACTION

The product allows access using the Go UP Introducer. The Suspension Loop must be inserted through the introducer from the T side and then the anchoring/suspension of the specimen. The Introducer is removed and subsequently the specimen suspension distance must be adjusted through the locking clips according to the surgeon's needs.

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## Instructions for Use

### Go Up

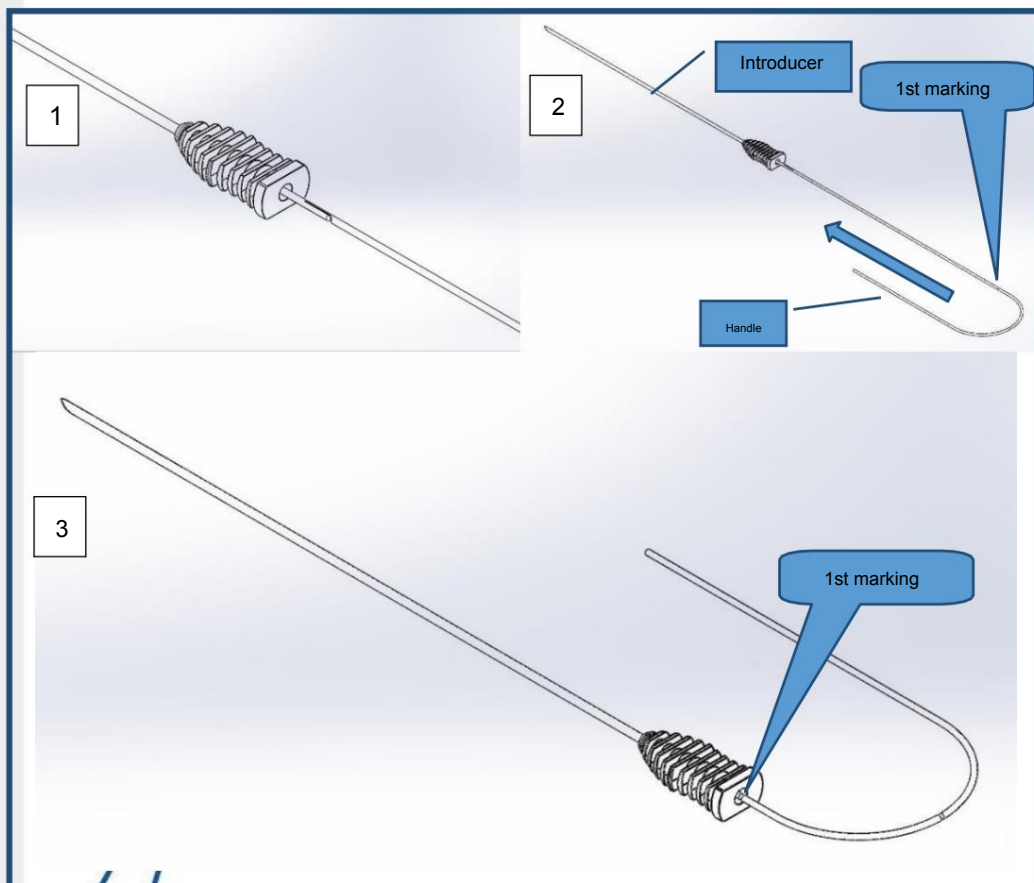
To remove the Go UP, cut the Suspension Strap near the clips and remove it.

them. Using a gripping instrument, pull the handle by the internal end, removing it completely through the trocar.

### HOW TO USE

WARNING: Product indicated for professional use only familiar with the technique.

- 1 – Make sure the packaging is not damaged ;
- 2 – Check the expiration date on the packaging;
- 3 – Open the packaging using aseptic techniques and place the display with the components in the sterile field;
- 4 – Before starting the procedure, make sure that all instruments are laparoscopic devices are compatible with the device.
- 5 - Carefully remove the protective tube from the Introducer;
- 6 - Insert the loop from the distal side into the introducer body and push until the first marking, as shown in figure 5.



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## Go Up Instructions for Use

Figure 1 - Illustration of the process of inserting the Go Up Handle into the Introducer up to the first marking.

**ATTENTION: Do not introduce the device before creating the pneumoperitoneum and placement of optics.**

7 - Hold the previously assembled introducer with the handle and drill the wall the patient's abdomen, following good surgical practices and, simultaneously, checking with the endoscope the trajectory and exit of the needle into the abdominal cavity.

8 - Hold the specimen that will be suspended under the supervision of the endoscope with a suitable instrument, position the introducer needle and pierce until cross the specimen from one side to the other.

9 - Hold the Introducer by the body and push the handle to the second marking, as shown in figure 6.

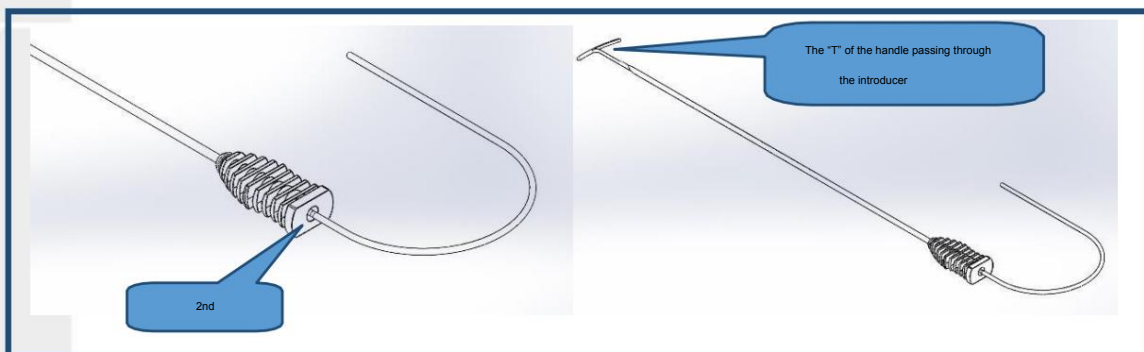


Figure 2 - Illustration of the process of inserting the Go Up Handle into the Introducer up to the second marking.

10 - Endoscopically determine whether the tip of the "T" shaped loop is fully exposed and activated.

**CAUTION: Do not pull the handle to suspend the specimen before removing the introducer to avoid damage.**

**WARNING: If the procedure is unsuccessful such as piercing of improper entry, tissue rupture, unintentional triggering**

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### Go Up

before piercing the tissue, do not use the Go UP if it has already been inserted and activated in the introducer until its second marking without being penetrated correctly in the specimen.

11 - Still holding the specimen with the instrument, use another atraumatic forceps to hold the tip of the handle in a “T” shape and remove the introducer by external route.

12 - From the outside of the cavity, insert the locking clips through the wider channel on the suspension loop, set the desired specimen height, with the locking clips resting on the outside of the cavity patient's abdominal perform the locking on the handle by moving the clips in towards its narrowest channel until it locks.

**WARNING: Use care when inserting the device to prevent possible lesions, always using the aid of endoscopic visualization.**

**CAUTION: Do not place the sharp tip of the introducer in contact with tissue that are not intended to be suspended.**

**WARNING: Use in conjunction with this product of any part, accessory or material that are not compatible is entirely user's responsibility.**

13 - Do not exert excessive force when lifting the specimen.

**WARNING: Avoid direct contact between electromedical equipment and the device, as this may damage it.**

### PROCEDURE FOR REMOVING THE DEVICE:

14 - Grasp the “T” shaped tip with a suitable instrument, as shown in figure 7.

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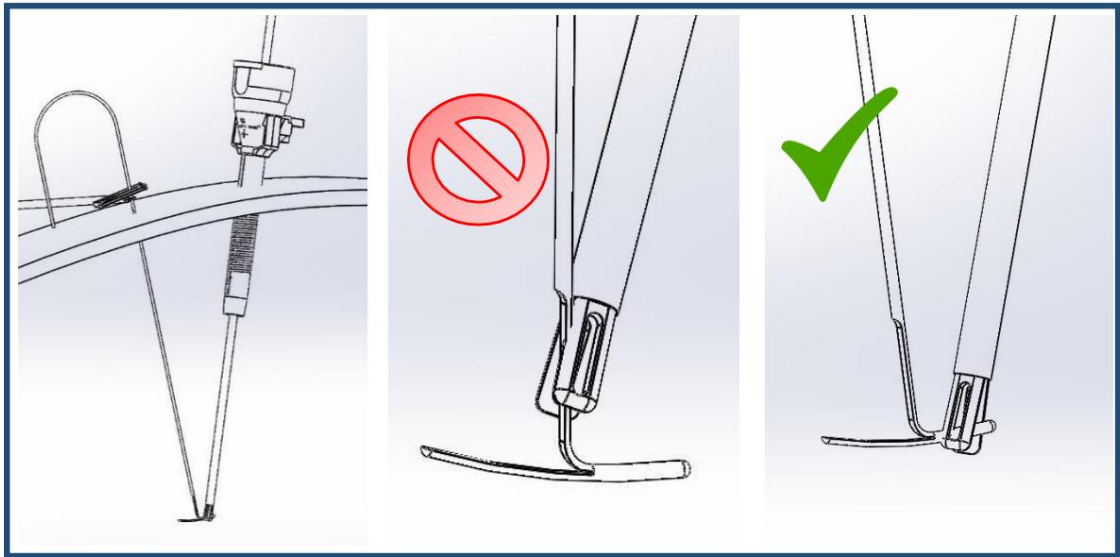


Figure 3 - Procedure for grasping the "T" of the handle.

15 - Cut the suspension strap close to the locking clips, as shown figure 8.

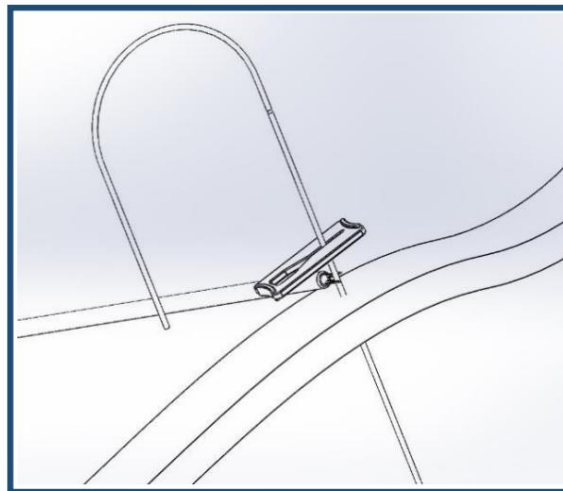


Figure 4 - Procedure for cutting the loop outside the abdominal cavity.

16 - Using the instrument, pull the "T" handle and remove it completely through a trocar, as shown in figure 9.

## Instructions for Use Go Up

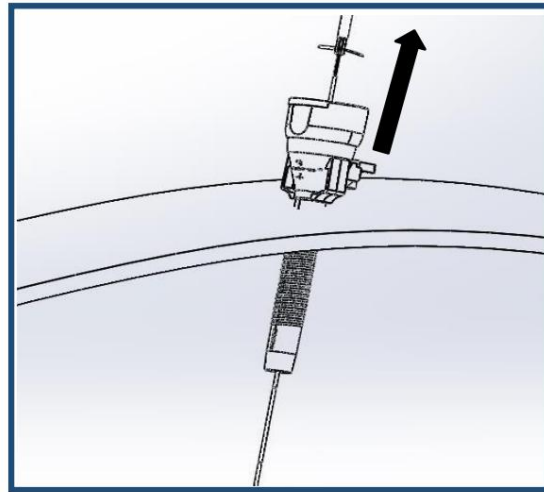


Figure 5 - Procedure for grasping the "T" of the loop and removing it through the trocar.

17 – Check that the strap has been completely removed from the abdominal cavity of the patient.

**CAUTION: Be careful not to leave any fragments of the device in the abdominal cavity.**

18 – Consider the instructions described above from items 6 to 17 for use of the second device (Suspension Strap and Locking Clips).

19 - After use, dispose of the device in accordance with current legislation.

### TECHNICAL INFORMATION

INTRODUCER: outer diameter 2.1mm, total length 270mm

TUBE: 265mm length and 3mm diameter

SUSPENSION STRAP: 1.5mm diameter, total length 263mm,  
distal end expanded by 25mm

CLIPS: 35mm length, 15mm width and 3.5mm thickness

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## Instructions for Use Go Up

### STERILIZATION

Go Up is supplied as a sterile product and must be removed from its original packaging only in the sterile surgical environment and be used immediately.

The sterilization method used is Ethylene Oxide Sterilization – ETO

Sterilization validity: 02 years from the date of manufacture.

### STORAGE AND TRANSPORTATION CARE

The product must be stored in a clean, ventilated place, protected from light. solar. Exposure to extreme temperature conditions and humidity. As a general recommendation, it is specified to keep it between 15°C and 45°C temperature and between 40% and 75% relative humidity. The conditions special storage, handling and conservation of the product must be followed to ensure that the components remain intact for the surgical procedure. Care with receipt, storage, transportation, cleaning and conservation of batch references must be adopted in conjunction with good storage practices and distribution of medical products.

The product must be transported and stored in a clean, airy place, protected from sunlight, heat sources and humidity.

### PRODUCT HANDLING

The product must be sterilized at the time of use. Do not use if the packaging is broken.

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## Instructions for Use

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This product must be handled carefully and individually, avoiding bumps or falls. Any product that has fallen or been improperly handled, or suspected of having suffered damage, must be separate and segregated.

After use, this product constitutes a biological risk. Disposal of the product must be carried out in accordance with municipal, state and local legislation or federal in force.

## WARNINGS

- The product is sterile, therefore use aseptic techniques for its handling.
- The product should only be used by trained professionals adequate, knowledge and experience in the use of procedures endoscopic and under the direction of qualified medical staff, familiar with the known risks and benefits of using of this device.
- Do not introduce the device before creating pneumoperitoneum and placement of optics.
- To perform the removal of any structure, the product must be correctly repositioned in the abdominal cavity.
- Incorrect introduction of the device into the abdominal cavity near large vessels can cause injuries and cause excessive bleeding. It can also result in organ perforations resulting from access without visualization of the pneumoperitoneum by the professional.
- The product is non-toxic and non-irritating, therefore it does not pose any risks to who handles it;

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## Go Up Usage

### Instructions •

Manufacturer Recommends Single Use. Reuse of the material may present risk of infection control, cause tissue irritation or poor operation.

- The product is sterilized in its final packaging, which must be handled with care so as not to cause folds and perforations. The sterilization validity must always be noted on the packaging. Sterilization is carried out using Ethylene Oxide - ETO.
- After use, this product may constitute a biological risk. The disposal of the product must be carried out in accordance with legislation municipal, state or federal legislation in force, always respecting the recommendations made for the treatment of hospital waste by the Health Authority. Local Environmental Control;
- The packaging should only be opened at the time of use, keeping aseptic techniques when handling the product.
- Do not pull the handle to suspend the specimen before removing the introducer so as not to damage it.
- The product does not have a similar purpose to suture thread, therefore it must be removed after use.
- The device must not be inserted/inserted directly into organs.

### PRECAUTIONS

- Check the integrity of the packaging and product before use;
- Use aseptic technique throughout the procedure ;
- Use according to the chosen medical protocol ;
- Dispose of in accordance with current health legislation.

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**Instructions for Use**  
**Go Up**  
**CONTRAINDICATIONS**

Always follow the product's instructions for use.

**ADVERSE EFFECTS**

Not applicable.

**COMPLAINTS AND CUSTOMER SERVICE**

Any customer or user of American Instruments products who has questions or if you would like further information about the products offered, you can contact contact American Instruments using the contact details contained in the instructions for use and labels on the product packaging.

**MANUFACTURED BY:**

**AMERICAN INSTRUMENTS EIRELI EPP**

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