Surgical Instruments Instructions For Use

1. General Information

The instructions for use contain the information for the safe and effective use of the product. Before use, please read it carefully and use the product according to the instructions. Place the instructions in a safe and convenient place. If you have any questions or comments about any information in this instruction, please contact Acuvu.

1.1 User qualification

The operator of the device must be physicians who have been trained in the clinical practice of hysteroscopy or medical staff with relevant specialty qualification.

1.2 Description of warning message

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed.

2. Intended Use

The products are semi-rigid and handheld manual surgical instruments introduced through the working channel of hysteroscope for cutting, grasping and manipulating tissue or foreign bodies during hysteroscopy procedures.

Intended use of Single action scissors

The single action scissors are intended for use in hysteroscopy procedures for cutting of soft tissue such as polyps from the uterine cavity.

Intended use of biopsy forceps and serrated forceps

The biopsy forceps and serrated forceps are intended for use in hysteroscopy procedure to obtain tissue samples for examination of tissue from the uterine cavity.

Intended use of alligator grasper and hook grasper

The alligator grasper and hook grasper are intended to be used in hysteroscopy procedure for retrieval of foreign bodies and tissues from the uterine cavity.

3. Contraindication

This product is contraindicated for use in:

- Inability to distend the uterus
- Cervical Stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Known pregnancy
- Known carcinoma of the cervix and/or the uterus
- Recent uterine perforation
- Known Pelvic Inflammatory Disease (PID)
- Medical contraindication or intolerance to anesthesia

4. Product Description

General Product Name: Surgical instruments

The device consists of handles, a shaft, and the head at the distal end. Opening and closing the device is done by pushing or pulling the handles away from/towards each other. The device drawing as shown in figure 1.

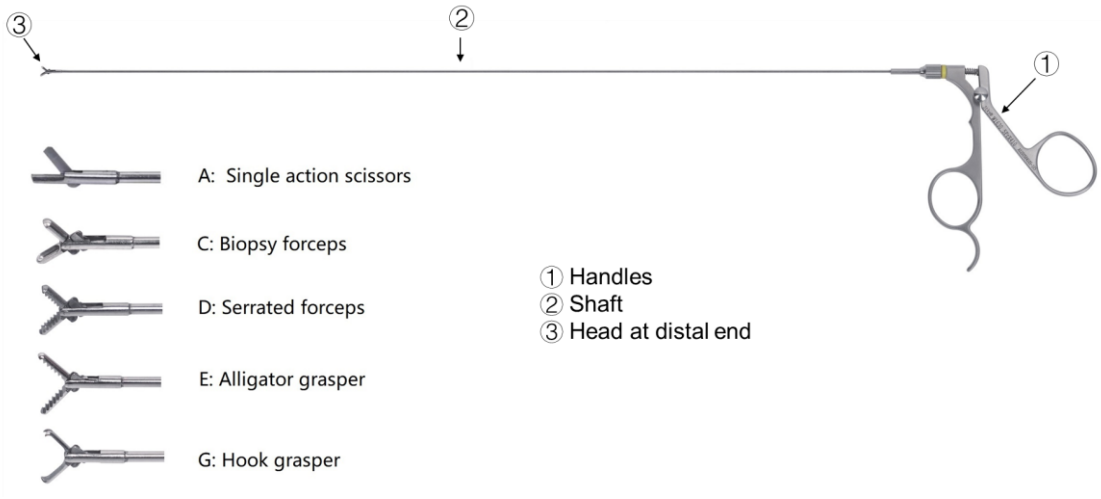


Figure 1 Drawing of surgical instruments

Product model list:

NO.	Model	Product Name	Working length	Outer diameter
1	RSI-370-5-A	Single action scissors	370mm	5Fr
2	RSI-370-7-A	Single action scissors	370mm	7Fr
3	RSI-370-9-A	Single action scissors	370mm	9Fr
4	RSI-370-5-C	Biopsy forceps	370mm	5Fr
5	RSI-370-7-C	Biopsy forceps	370mm	7Fr
6	RSI-370-9-C	Biopsy forceps	370mm	9Fr
7	RSI-370-5-D	Serrated forceps	370mm	5Fr
8	RSI-370-7-D	Serrated forceps	370mm	7Fr
9	RSI-370-9-D	Serrated forceps	370mm	9Fr
10	RSI-370-5-E	Alligator grasper	370mm	5Fr
11	RSI-370-7-E	Alligator grasper	370mm	7Fr
12	RSI-370-9-E	Alligator grasper	370mm	9Fr
13	RSI-370-5-G	Hook grasper	370mm	5Fr
14	RSI-370-7-G	Hook grasper	370mm	7Fr
15	RSI-370-9-G	Hook grasper	370mm	9Fr

5. Warnings and precautions

WARNINGS

- The devices are not sterile upon delivery, the use of non-sterile device poses a risk of infection to patients and users.
- Inspect and test before use. Unfold the handle of device. Open and close the head of device by actuating the handle and confirm the function of the device.
- Improper use and damaged device can lead to injuries to the patient. Device must be checked immediately before and after every use to ensure that they are complete and free of damage,
- Care must be taken not to leave missing or broken-off components inside the patient.
- DO NOT overload the device with too much mechanical stress. Overloading may cause the device break, bend or malfunction, and consequently injure the patient or user.
- Before each use, the device shall be cleaned and sterilized according to the methods provided in this manual.
- Device stored in inappropriate environment may cause device damage.
- The device should be disposed of according to the medical waste treatment regulations of local medical institutions. Improper dispose of device might pollute the environment and cause biological hazards.

6. Operation

- Inspect the device to ensure that the correct device is chosen and the device is sterilized before use.
- Inspect the head and shaft for any obvious damage prior to use. DO NOT attempt to use the device if damaged.
- Check the open/close function of the device by actuating the handle.
- Close the head of device before inserting the device into the working channel of hysteroscope.
- Slowly insert the device into the working channel of hysteroscope until the head is visualized on the vision of hysteroscope.

- Open and close the device by activating the handles. Use only enough force to cut or grasp the tissue.
- Apply gentle force on the handles as the device are extracted from the working channel.
- Process the used products according to the cleaning and sterilization procedures.

7. Cleaning

Cleaning is recommended immediately after use. Drying of organic residues will stick to the mechanical surface and cause damage to the device. Wear rubber gloves to prevent infection or skin damage.

Pre-Cleaning

- Wipe the surfaces of the device with a compress or disposable cloth to remove gross soiling and residues.
- Open the head of device manually by actuating the handles of device, carefully clean the head of device in opening state. Make sure the residues are removed from the jaws of head.
  Note*:* The head of device are closed in the normal state. Acuvu recommend two methods in order to open the head for sake of effective cleaning. Please refer to method 1 and method 2 in this manual.
- Rinse the device thoroughly with running clean water.
- To dissolve dried organic residues, the device must be immersed in cold water for enough time.
- Any visible contamination or heavy soiling must be removed by cleaning the surfaces under running water with the aid of a brush or sponge.

Machine Cleaning

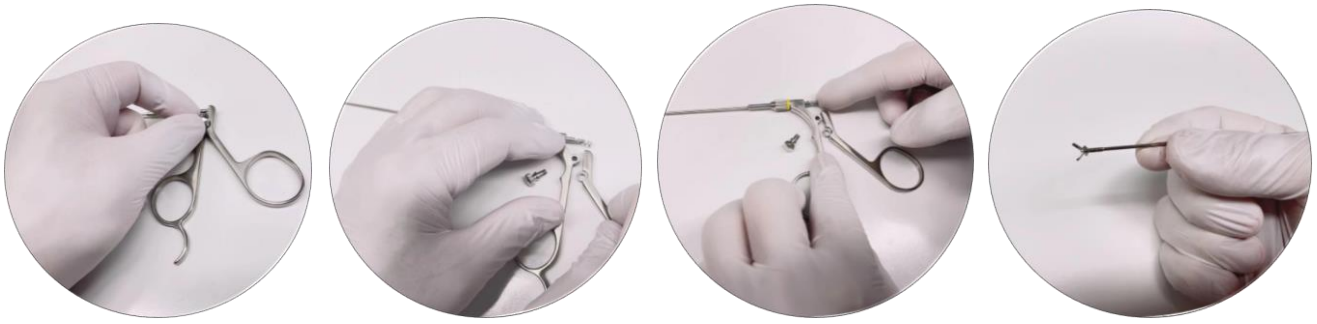
- Place the device in an ultrasonic bath containing the cleaning solution.
- The device shall be ultrasonically cleaned follow the instructions of ultrasonic cleaning machine.
- Thoroughly rinse the device with a large amount of clean water, and then let it dry.
- Test the function of the device by opening and closing the head of the device. Make sure the head moves smoothly and the mechanical parts at the head are clean without visible stains.

Note: *Two methods for opening of head during Pre-cleaning.*

Method 1: The device be separated into parts and heads are opened.

Please follow below steps for separation of the device.

a. Unscrew the knob on the handle of device as shown in figure 2a;
b. Disassemble the handle of device as shown in figure 2b;
c. Push the rod of inner shaft to the end as shown in figure 2c;
d. Make sure the head opened as shown in figure 2d;
e. Inspect the cleanliness of head and reassemble the device for machine cleaning and sterilization.



(a) (b) (c) (d)

Figure 2 The illustration of method 1.

Method 2: Use C-Clamp to expand the handles of device and heads are opened

Please follow below steps for expanding of the handles.

a. Using the C-Clamp provided associate with devices as shown in figure 3a;
b. Manually press the C-Clamp inward and stuck it to handles as shown in figure 3b;

c. Make sure the head opened as shown in figure 3c actuated by innate expanding of C-Clamp;

d. Detach the C-Clamp by holding and inward pressing the arm from the handles, as shown in figure 3d.

(a) (b) (c) (d)

Figure 3 The illustration of method 2.

8. Sterilization

8.1 Packaging

8.1.1 Non-woven Fabric Wrap Method

Double wrap the item using non-woven fabric sterilization wrap according to the wrap manufacturer's instructions. The following general guidance applies unless otherwise specified by the wrap manufacturer or facility policy:

1. Place the wrapping fabric diagonally on the work surface, with the bottom corner pointing toward the front. Position the surgical instrument or the sterilization tray to be wrapped in the center of the wrap, aligned perpendicular to an imaginary line connecting the top and bottom corners.
2. Fold the bottom corner over and then fold it back to form a flap.
3. Fold the left corner over and then fold it back to form a flap.
4. Fold the right corner over, overlapping the previous fold, and then fold it back to form a flap
5. Fold the top corner over the item, tucking the flap into the previously formed side folds. Leave a small visible tab to facilitate opening in a sterile environment.
6. Repeat the above steps to apply a second wrap layer in the same manner. Secure the final package with two sterilization indicator tapes

8.1.2 Paper-plastic Sterilization Pouch Method

1. Fill the sterilization pouch at most ¾ of the volume to allow air evacuation and steam sterilant penetration.
2. Ensure at least one inch of space is available around the sides of the pouch for ventilation.
3. Seal the pouch securely according to the pouch manufacturer’s instructions.

8.2 Sterilization Configuration

The sterilization method must be selected according to the national sterilization regulations and must be compliant with the sterilization machine manufacturers’ instructions.

The following sterilization procedure has been validated by AcuVu

Sterilization Method: Steam sterilization

Sterilization configuration: 121^{o}C temperature for 30 minutes and 35 minutes dry time.

132^{o}C temperature for 4 minutes and 35 minutes dry time.

9. Production date and Reprocessing Limit

Production date: see label

The product reprocessing limit is largely determined by operation methods, reprocessing methods, the chemicals used and any damage resulting from use or reprocessing.

10. Operating and Storage Condition

10.1 Operating Conditions

Temperature : +10° C～+45° C; Relative humidity: 30%～70%

10.2 Storage Condition

Temperature : -30° C～+55° C ; Relative humidity : 10%～90%

11. Symbols and labels

	Catalog number		General Warning sign
	Consult Instructions for Use		Date of Manufacture
	Batch code		Keep dry
	Read operators manual		Manufacturer
	Manufacturer brand logo		Non-Sterile
	Humidity limitation		Temperature limit

12. Manufacturer Information

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