

## Rigid Endoscope

## Small Diameter, Big Vision

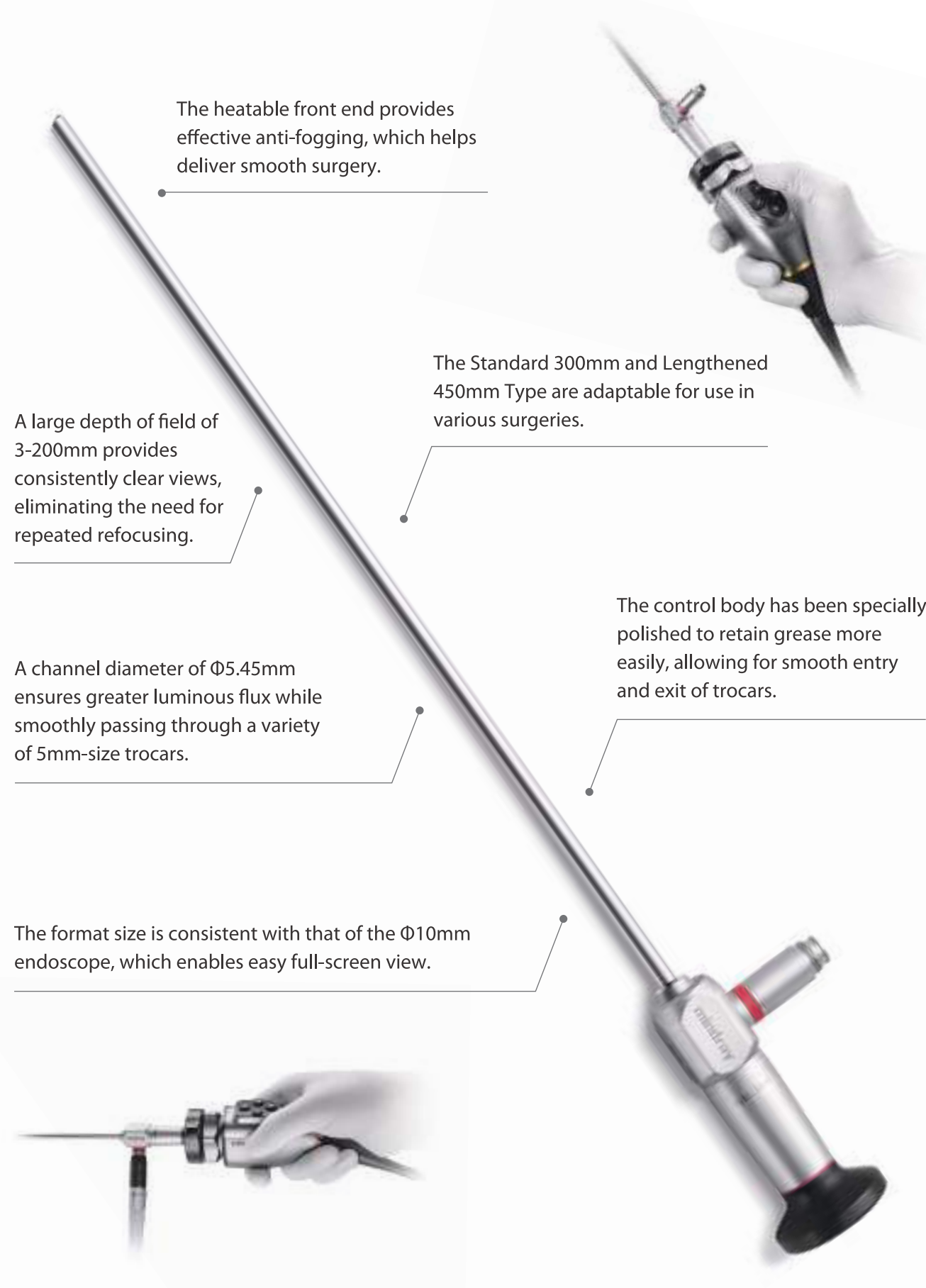


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Location: Moldova

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## Small Diameter, Big Vision



The heatable front end provides effective anti-fogging, which helps deliver smooth surgery.

A large depth of field of 3-200mm provides consistently clear views, eliminating the need for repeated refocusing.

The Standard 300mm and Lengthened 450mm Type are adaptable for use in various surgeries.

A channel diameter of  $\Phi 5.45\text{mm}$  ensures greater luminous flux while smoothly passing through a variety of 5mm-size trocars.

The control body has been specially polished to retain grease more easily, allowing for smooth entry and exit of trocars.

The format size is consistent with that of the  $\Phi 10\text{mm}$  endoscope, which enables easy full-screen view.



## Rigid Endoscope

### Standard 5mm Type

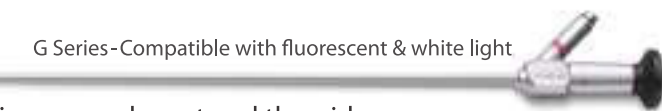


G Series- Compatible with fluorescent & white light

Recommended Surgery: Single-port gynecologic surgery, thoracic surgery

| Product | Diameter | Working Length | Field of View | Code     |
|---------|----------|----------------|---------------|----------|
| 0° →    | 5.45mm   | 300mm          | 85°           | G 00500A |
| 30° ↗   | 5.45mm   | 300mm          | 85°           | G 00530A |

### Lengthened 5mm Type



G Series- Compatible with fluorescent & white light

Recommended Surgery: Single-port gynecologic surgery, single-port bariatric surgery, breast and thyroid surgery

| Product | Diameter | Working Length | Field of View | Code     |
|---------|----------|----------------|---------------|----------|
| 0° →    | 5.45mm   | 450mm          | 85°           | G 10500A |
| 30° ↗   | 5.45mm   | 450mm          | 85°           | G 10530A |

G Series- Compatible with fluorescent & white light

### Standard 10mm Type



M Series- Applicable with white light

Recommended Surgery: General Surgery

| Product | Diameter | Working Length | Field of View | Code                |
|---------|----------|----------------|---------------|---------------------|
| 0° →    | 10mm     | 321mm          | 80°           | M 01000A / G 01000A |
| 30° ↗   | 10mm     | 321mm          | 80°           | M 01030A / G 01030A |

## Rigid Endoscope Tray



| Product Name               | Placed Items                              | Dimensions (mm) | Code       |
|----------------------------|-------------------------------------------|-----------------|------------|
| Small Rigid Endoscope Tray | Standard 5 or 10mm Rigid Endoscope        | 496×90×44       | X TR500944 |
| Long Rigid Endoscope Tray  | Lengthened 5mm or 3D Electronic Endoscope | 643×158×75      | X TR641675 |

## **Rigid Endoscope**

### **Operator's Manual**

(M 01030A/M 01000A/M 01030PA/M 01000PA/G 01030A/  
G 01000A/G 01030PA/G 01000PA/M 00530A/G 00530A/  
M 00500A/G 00500A/M 10530A/G 10530A/M 10500A/  
G 10500A/M 00530PA/G 00530PA/M 00500PA/G 00500PA/  
M 10530PA/G 10530PA/M 10500PA/G 10500PA)



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- Release time: 2023-5
- Revision: 1.0



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#### NOTE

- “PA” in the model indicates that endoscope of this model is not configured with light cable adapter, Storz.
  - In addition to the difference of basic parameters above, there are differences in some optical parameters between the 10 mm series and 5 mm series.
- 

### 2.11 Product Components

Taking M 00500A as an example, this product consists of the following parts:



- |     |                                                                       |
|-----|-----------------------------------------------------------------------|
| (1) | Eyepiece                                                              |
| (2) | Main body                                                             |
| (3) | Light cable connector (available for ACMI/Olympus Pro light cables)   |
| (4) | Light cable adapter (available for Mindray/Richard Wolf light cables) |
| (5) | Light cable adapter (available for STORZ light cables)                |
| (6) | Objective lens                                                        |

### 3.5 Inspection Description

Before cleaning, disinfecting, or sterilizing the equipment, check the equipment using the following steps.

#### 3.5.1 Visual Inspection

1. Check whether the sapphire surfaces of the eyepiece and objective lens are damaged, cracked or contaminated. Ensure that they are clean and smooth.
2. Check whether the lens body is bent, sunken, cracked or contaminated, ensuring it is clean and intact.
3. Ensure there is no rough surface, sharp edges or protrusions on the parts that will be put inside the patient.
4. Check whether all moving parts and sealed parts function well.
5. If any damage is detected, refer to **5.1 Common Faults and Solutions** for solutions. If the problem persists, contact your service personnel.

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#### WARNING

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- Using this product with any sharp edges or broken surfaces will put patients at risk. So before each use, check and ensure there are no unintended rough surfaces, sharp edges or protrusions which may cause harm.
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#### 3.5.2 Inspection of Fiber Optics

1. Put the objective lens of the endoscope in front of the eye.
2. Point the objective lens at a bright light source, such as an indoor lighting source, other than a cold light source, and slightly move the distal end of the endoscope.
3. Observe whether any black dots or distortion exists in your field of view. If yes, do not use the endoscope and contact your service personnel.

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**NOTE**

- Do not use the equipment if surfaces of the fiber optics, sapphire, or lens body have been damaged or if there are stains on the surfaces. For any problem, contact your service personnel.
- 

**3.5.3 Inspection of Image Quality**

1. Place a piece of paper with text about 50 mm in front of the objective lens.
2. Observe whether image blurring, loss of focus, or dark area exists in your field of view. If yes, replace the endoscope.

**3.6 Device Connection**

This equipment can be connected to devices including endoscopic camera system and light source, assisting in endoscopic diagnosis and treatment.

The equipment meets the requirements of type CF applications. Other medical devices used at the same time as this equipment during the surgery should at least meet the requirements for type CF applications.

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**WARNING**

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- Before use, the operator must check the equipment, cables and accessories, to ensure they work properly and safely.
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**3.7 Connecting the Endoscope**

1. Connect the connector (to endoscope) of the light cable to the light cable connector of the endoscope, as shown in the figure below:

- The product is very sensitive to impacts at high temperature, so avoid impacting and vibrating the product at high temperatures.

Before sterilization, please place the endoscope in the sterilization tray, and then wrap with two polypropylene sterilization wrap.

Recommended sterilization methods that have been verified:

| Sterilization Type           | Applicable Model                     |
|------------------------------|--------------------------------------|
| Autoclave sterilization      | M 01030A, M 01000A                   |
| Ethylene oxide sterilization | M 01030A, M 01000A, M 01030, M 01000 |

#### 4.4.1 Autoclave sterilization

For the loading method of autoclave sterilization, please refer to the operating instructions of the corresponding sterilizer. As the sterilizer and its operating conditions may affect sterilization, it is suggested that the sterilization process be reconfirmed and monitored before sterilization in accordance with the international standards (such as ISO 17665), national standards, or hospital sterilization management rules related to autoclave sterilization.

The sterilizer must be certified in accordance with DIN EN 285 and tested in accordance with DIN EN ISO 17665.

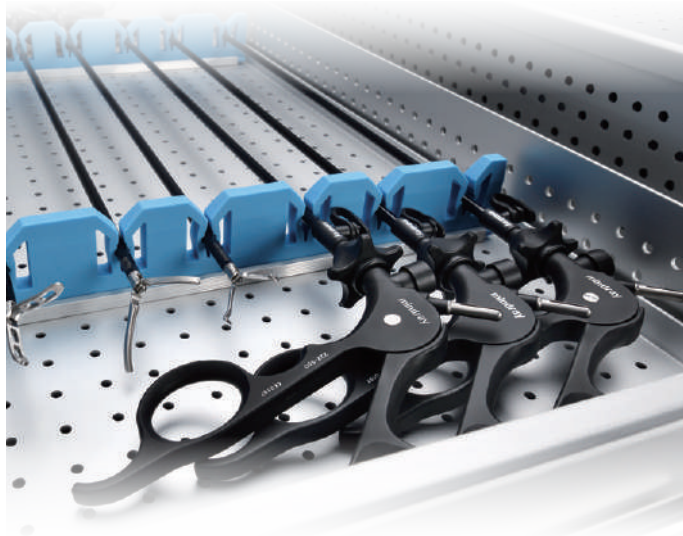
Autoclave sterilization parameters are as follows:

| Sterilization process | Temperature | Exposure time |
|-----------------------|-------------|---------------|
| Gravity displacement  | 121 °C      | 30 min        |
| Pre-vacuum            | 134 °C      | 5 min         |

Sterilization tolerance cycle: 500 times.

## Reusable Laparoscopic Instruments

## User Friendly & Future Proof





## Trocars

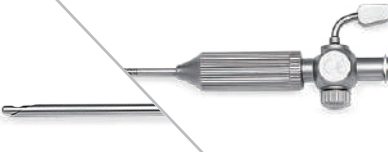


| Product                                                                             | Description                   | Dimension | Code      |   |
|-------------------------------------------------------------------------------------|-------------------------------|-----------|-----------|---|
|    | Pyramidal Trocar              | φ 5X95    | 221-51155 | 👍 |
|                                                                                     |                               | φ 10X95   | 221-01155 | 👍 |
|                                                                                     |                               | φ 12X95   | 221-81155 |   |
|                                                                                     |                               | φ 5X150   | 221-53155 | 👍 |
|                                                                                     |                               | φ 10X150  | 221-03155 | 👍 |
|                                                                                     |                               | φ 12X150  | 221-83155 | 👍 |
|  | Auto Shield Trocar            | φ 5X95    | 221-51255 |   |
|                                                                                     |                               | φ 10X95   | 221-01255 |   |
|                                                                                     |                               | φ 12X95   | 221-81255 |   |
|                                                                                     |                               | φ 5X150   | 221-53255 |   |
|                                                                                     |                               | φ 10X150  | 221-03255 |   |
|                                                                                     |                               | φ 12X150  | 221-83255 |   |
|  | Pyramidal Trocar with Screw   | φ 5X95    | 221-51165 |   |
|                                                                                     |                               | φ 10X95   | 221-01165 |   |
|                                                                                     |                               | φ 12X95   | 221-81165 |   |
|  | Auto Shield Trocar with Screw | φ 5X95    | 221-51265 |   |
|                                                                                     |                               | φ 10X95   | 221-01265 |   |
|                                                                                     |                               | φ 12X95   | 221-81265 |   |

## Trocars

- To avoid blood contamination when inserting the telescope and to reduce times of cleaning the tip of the telescope by controlling the sealing flap opening and closing.



| Product                                                                               | Description    | Dimension  | Code      |   |
|---------------------------------------------------------------------------------------|----------------|------------|-----------|---|
|  | Veress Needle  | φ 2X120    | 221-21127 |   |
|                                                                                       |                | φ 2.7X150  | 221-27157 | 👍 |
|  | Reducer Sleeve | φ 10 - φ 5 | 221-01785 |   |
|                                                                                       |                | φ 12 - φ 5 | 221-81785 |   |
|  | Sealing Cap    | φ 5        | 221-50925 | 👍 |
|                                                                                       |                | φ 10       | 221-00925 | 👍 |
|                                                                                       |                | φ 12       | 221-80925 | 👍 |
|  | Reducer        | φ 10 - φ 5 | 221-00725 | 👍 |
|                                                                                       |                | φ 12 - φ 5 | 221-80725 | 👍 |
|  | Reducer        | φ 10 - φ 5 | 221-00715 |   |

# The "Relia" Reusable Electrode Surgical Instruments



## Safe

Insulated sleeve exposes a shorter metal base to avoid the accidental damage caused by electrical leakage.



## Durable

Strictly selected materials plus special production processes greatly extend the product's life.



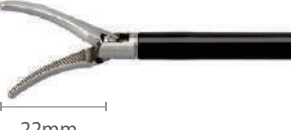
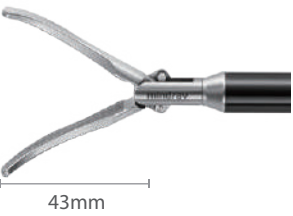
## Ergonomic

One-click to disassemble into three parts for more thorough cleaning and sterilization.



## Dissecting and Grasping Forceps

- **Diamond serration clamp teeth**  
Stronger grasping force with less tissue damage
- **No obvious bulge at the opening joint**  
Reduce blood and tissue residues, easy to clean and reduce cross infection
- **Shorter metal base**  
Less unintentional electrical injury

| Product                                                                                     | Description                                           | Dimension              | Code       |   |
|---------------------------------------------------------------------------------------------|-------------------------------------------------------|------------------------|------------|---|
| <br>16mm   | KELLY Dissecting and Grasping forceps, Maryland       | φ 5X360                | 222-5S3013 | 👍 |
|                                                                                             |                                                       | φ 5X360, With Ratchet  | 222-5T3013 |   |
|                                                                                             |                                                       | φ 5X430                | 222-5S4013 |   |
|                                                                                             |                                                       | φ 5X430, With Ratchet  | 222-5T4013 |   |
| <br>22mm   | KELLY Dissecting and Grasping forceps, long, Maryland | φ 5X360                | 222-5S3023 | 👍 |
|                                                                                             |                                                       | φ 5X360, With Ratchet  | 222-5T3023 |   |
|                                                                                             |                                                       | φ 5X430, With Ratchet  | 222-5T4023 |   |
| <br>16mm | Dissecting and Grasping forceps, right-angled         | φ 5X360                | 222-5S3123 | 👍 |
|                                                                                             |                                                       | φ 5X360, With Ratchet  | 222-5T3123 |   |
|                                                                                             |                                                       | φ 5X430, With Ratchet  | 222-5T4123 |   |
| <br>23mm | Straight Dissecting and Grasping forceps, atraumatic  | φ 5X360                | 222-5S3043 |   |
|                                                                                             |                                                       | φ 5X360, With Ratchet  | 222-5T3043 |   |
| <br>43mm | Dissecting and Grasping forceps, atraumatic           | φ 10X360               | 222-0S3103 |   |
|                                                                                             |                                                       | φ 10X360, With Ratchet | 222-0T3103 |   |
| <br>26mm | Dissecting and Grasping forceps, right-angled         | φ 10X360               | 222-0S3133 | 👍 |
|                                                                                             |                                                       | φ 10X360, With Ratchet | 222-0T3133 |   |

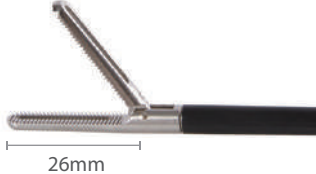
## Grasping Forceps



No Ratchet



With Ratchet

| Product                                                                                       | Description                                             | Dimension             | Code       |   |
|-----------------------------------------------------------------------------------------------|---------------------------------------------------------|-----------------------|------------|---|
| <br>18mm   | Bowel Grasper, fenestrated, short                       | φ 5X360               | 222-5S3213 | 👍 |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3213 |   |
| <br>24mm   | Atraumatic Grasping forceps                             | φ 5X360               | 222-5S3633 | 👍 |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3633 |   |
|                                                                                               |                                                         | φ 5X430, With Ratchet | 222-5T4633 |   |
| <br>27mm  | CROCE-OLMI Grasping forceps, atraumatic, curved         | φ 5X360               | 222-5S3453 | 👍 |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3453 |   |
|                                                                                               |                                                         | φ 5X430, With Ratchet | 222-5T4453 |   |
| <br>26mm | Grasping forceps, w specially fine atraumatic serration | φ 5X360               | 222-5S3473 |   |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3473 |   |
|                                                                                               |                                                         | φ 5X430               | 222-5S4473 |   |
|                                                                                               |                                                         | φ 5X430, With Ratchet | 222-5T4473 |   |
| <br>37mm | Bowel Grasper, fenestrated                              | φ 5X360               | 222-5S3303 | 👍 |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3303 |   |
| <br>18mm | BABCOCK Grasping forceps                                | φ 5X360               | 222-5S3553 |   |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3553 | 👍 |
| <br>14mm | Grasping forceps, 2X4 teeth                             | φ 5X360               | 222-5S3393 |   |
|                                                                                               |                                                         | φ 5X360, With Ratchet | 222-5T3393 |   |



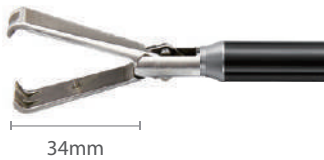
# Grasping Forceps



No Ratchet



With Ratchet

| Product                                                                                     | Description                                      | Dimension              | Code       |
|---------------------------------------------------------------------------------------------|--------------------------------------------------|------------------------|------------|
| <br>28mm   | Grasping forceps, atraumatic                     | φ 5X360                | 222-5S3333 |
|                                                                                             |                                                  | φ 5X360, With Ratchet  | 222-5T3333 |
| <br>15mm   | VANCAILLIE Adhesion Forceps, one jaw fenestrated | φ 5X360                | 222-5S3493 |
|                                                                                             |                                                  | φ 5X360, With Ratchet  | 222-5T3493 |
| <br>15mm  | MANHES biopsy forceps                            | φ 5X360                | 222-5S3903 |
|                                                                                             |                                                  | φ 5X360, With Ratchet  | 222-5T3903 |
| <br>14mm | MANHES Grasping forceps, "tiger-jaws", 2X4 teeth | φ 5X360                | 222-5S3363 |
|                                                                                             |                                                  | φ 5X360, With Ratchet  | 222-5T3363 |
| <br>16mm | Claw forceps, 2X3 teeth, short                   | φ 10X360               | 222-0S3403 |
|                                                                                             |                                                  | φ 10X360, With Ratchet | 222-0T3403 |
| <br>34mm | SAWALHE Tissue Grasping forceps                  | φ 10X360               | 222-0S3423 |
|                                                                                             |                                                  | φ 10X360, With Ratchet | 222-0T3423 |
| <br>30mm | BABCOCK Grasping forceps                         | φ 10X360               | 222-0S3573 |
|                                                                                             |                                                  | φ 10X360, With Ratchet | 222-0T3573 |

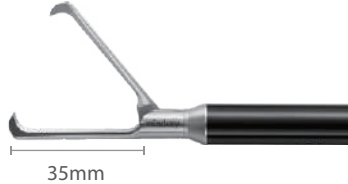
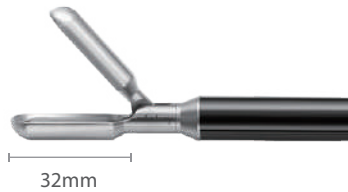
# Grasping Forceps



No Ratchet



With Ratchet

| Product                                                                                       | Description                                        | Dimension              | Code       |   |
|-----------------------------------------------------------------------------------------------|----------------------------------------------------|------------------------|------------|---|
| <br>35mm   | Claw forceps, 2X3 teeth                            | φ 10X360               | 222-0S3413 |   |
|                                                                                               |                                                    | φ 10X360, With Ratchet | 222-0T3413 | 👍 |
| <br>32mm   | Spoon forceps                                      | φ 10X360               | 222-0S4883 |   |
|                                                                                               |                                                    | φ 10X360, With Ratchet | 222-0T4883 | 👍 |
| <br>13mm  | VANCAILLIE Oviduct Forceps                         | φ 5X360                | 222-5S3583 | 👍 |
|                                                                                               |                                                    | φ 5X360, With Ratchet  | 222-5T3583 |   |
| <br>18mm | Dissecting and Grasping forceps, "alligator jaws"  | φ 5X360                | 222-5S3773 |   |
|                                                                                               |                                                    | φ 5X360, With Ratchet  | 222-5T3773 |   |
| <br>31mm | DeBAKEY Grasping forceps, curved and slender jaws  | φ 5X360                | 222-5S3813 |   |
|                                                                                               |                                                    | φ 5X360, With Ratchet  | 222-5T3813 |   |
| <br>19mm | Grasping forceps, atraumatic, spoon-shaped         | φ 5X360                | 222-5S3223 |   |
|                                                                                               |                                                    | φ 5X360, With Ratchet  | 222-5T3223 |   |
| <br>14mm | MANHES Dissecting and Grasping forceps, "duckbill" | φ 5X360                | 222-5S3283 |   |
|                                                                                               |                                                    | φ 5X360, With Ratchet  | 222-5T3283 |   |

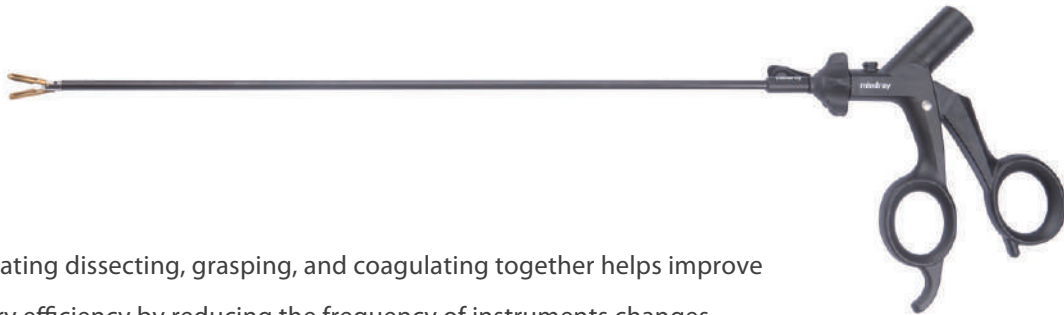
# Monopolar Scissors



- **Sharp**  
The sharpest blade enables fast cutting.
- **Smooth**  
Involute design of blade line ensures more smooth cutting.
- **Durable**  
The vacuum heat treatment process makes sure that the metal hardness control accuracy reaches HRC1 (Rockwell hardness), increasing the metal life by 3-4 times compared with the traditional method.

| Product                                                                                     | Description                                     | Dimension | Code       |   |
|---------------------------------------------------------------------------------------------|-------------------------------------------------|-----------|------------|---|
| <br>15mm | METZENBAUM Scissors, curved                     | φ 5X360   | 222-5S3022 | 👍 |
|                                                                                             |                                                 | φ 5X430   | 222-5S4022 | 👍 |
| <br>20mm | Scissors, spoon-shaped blades, serrated, curved | φ 5X360   | 222-5S3012 |   |
|                                                                                             |                                                 | φ 5X430   | 222-5S4012 |   |
| <br>15mm | Scissors, straight                              | φ 5X360   | 222-5S3092 |   |
|                                                                                             |                                                 | φ 5X430   | 222-5S4092 |   |

# Bipolar Dissecting Forceps



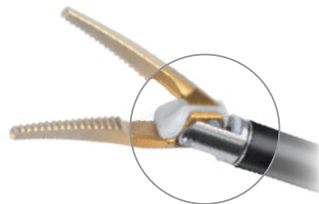
Integrating dissecting, grasping, and coagulating together helps improve surgery efficiency by reducing the frequency of instruments changes.



- **Innovative anti-sticking:**  
Sticking prevention with coated jaw.



- **Strong grasping:**  
Enhanced force with wider opening angle to achieve better grasping.



- **Guaranteed Safety:**  
Advanced insulation design guarantees the safety and reliability of bipolar coagulation.

| Product                                                                                       | Description                                | Dimension | Code       |   |
|-----------------------------------------------------------------------------------------------|--------------------------------------------|-----------|------------|---|
| <br>15mm | Bipolar Straight Dissecting Forceps        | φ 5X360   | 222-5S3011 | 👍 |
|                                                                                               |                                            | φ 5X430   | 222-5S4011 | 👍 |
| <br>15mm | Bipolar Curved Maryland Dissecting Forceps | φ 5X360   | 222-5S3021 | 👍 |
|                                                                                               |                                            | φ 5X430   | 222-5S4021 |   |



# Monopolar Electrodes



| Product                                                                             | Description                       | Dimension | Code      |   |
|-------------------------------------------------------------------------------------|-----------------------------------|-----------|-----------|---|
|    | Hook Tip Coagulation Electrode    | φ 5X330   | 222-51110 | 👍 |
|    | Ball Tip Coagulation Electrode    | φ 5X330   | 222-51220 |   |
|    | Spatula Tip Coagulation Electrode | φ 5X330   | 222-51440 | 👍 |
|  | Rod Tip Coagulation Electrode     | φ 5X330   | 222-51610 | 👍 |

# Cables

All cables are autoclavable.

| Product                                                                             | Description     | Dimension | Code    |   |
|-------------------------------------------------------------------------------------|-----------------|-----------|---------|---|
|  | Monopolar cable | 3200mm    | 999-030 | 👍 |
|  | Bipolar Cable   | 3200mm    | 999-031 | 👍 |



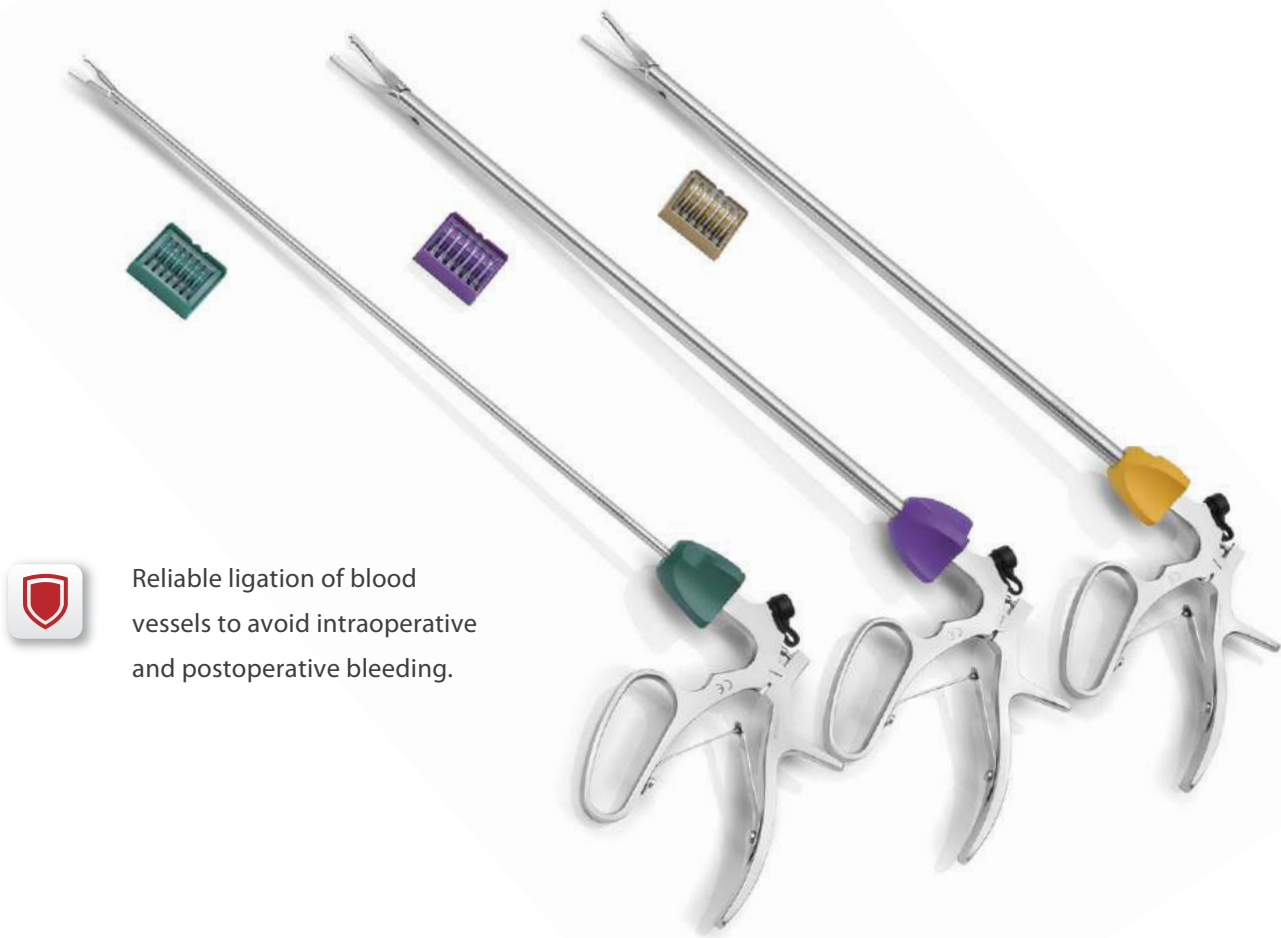
# Instrument Trays



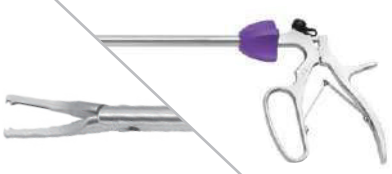
| Product                                                                               | Description                        | Dimension   | Code       |   |
|---------------------------------------------------------------------------------------|------------------------------------|-------------|------------|---|
|  | Double-decker Instrument Tray      | 540X250X100 | X TR5425A0 |   |
|                                                                                       | Long Double-decker Instrument Tray | 600X250X100 | X TR6025A0 | 👍 |
|                                                                                       | Long Three-decker Instrument Tray  | 600X250X140 | X TR6025E4 |   |



## Clip Appliers



 Reliable ligation of blood vessels to avoid intraoperative and postoperative bleeding.

| Product                                                                             | Description                                        | Dimension | Code      |                                                                                       |
|-------------------------------------------------------------------------------------|----------------------------------------------------|-----------|-----------|---------------------------------------------------------------------------------------|
|  | Endo Applier for Medium Large polymer locking Clip | φ 5X330   | 221-55636 |  |
|  | Endo Applier for Large polymer locking Clip        | φ 10X330  | 221-05646 |  |
|  | Endo Applier for Extra Large polymer locking Clip  | φ 10X330  | 221-05656 |  |

## Clip Appliers

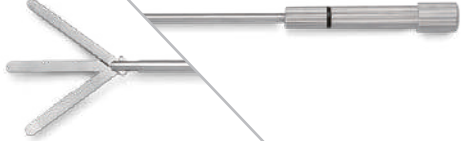
| Product                                                                               | Description                                                | Dimension | Code      |                                                                                     |
|---------------------------------------------------------------------------------------|------------------------------------------------------------|-----------|-----------|-------------------------------------------------------------------------------------|
|    | Endo Applier for Small Titanium Clip, Single action        | φ 5X330   | 221-55116 |  |
|    | Endo Applier for Medium Titanium Clip, Single action       | φ 10X330  | 221-05126 |                                                                                     |
|    | Endo Applier for Medium Large Titanium Clip, Single action | φ 10X330  | 221-05136 |  |
|   | Endo Applier for Large Titanium Clip, Single action        | φ 10X330  | 221-05146 |                                                                                     |
|  | Open Surgery Applier for Small Titanium Clip               | 28 cm     | 221-00516 |                                                                                     |
|  | Open Surgery Applier for Small Titanium Clip               | 18 cm     | 221-01516 |                                                                                     |
|  | Open Surgery Applier for Medium Titanium Clip              | 28 cm     | 221-00526 |                                                                                     |
|  | Open Surgery Applier for Medium Titanium Clip              | 23 cm     | 221-01526 |                                                                                     |
|  | Open Surgery Applier for Medium Large Titanium Clip        | 28 cm     | 221-00536 |                                                                                     |
|  | Open Surgery Applier for Large Titanium Clip               | 28 cm     | 221-00546 |                                                                                     |



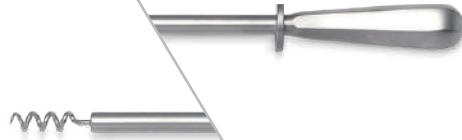
## ENDO-Retractors

| Product                                                                           | Description    | Dimension | Code      |                                                                                     |
|-----------------------------------------------------------------------------------|----------------|-----------|-----------|-------------------------------------------------------------------------------------|
|  | ENDO-Retractor | φ 5X360   | 221-53013 |                                                                                     |
|  | ENDO-Retractor | φ 5X360   | 221-53023 |  |

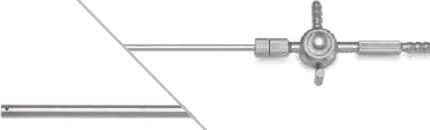
## Fans Dissecting Forceps

| Product                                                                             | Description        | Dimension | Code      |                                                                                       |
|-------------------------------------------------------------------------------------|--------------------|-----------|-----------|---------------------------------------------------------------------------------------|
|  | 3 Finger Retractor | φ 5X330   | 221-55923 |                                                                                       |
|  | 5 Finger Retractor | φ 10X330  | 221-05923 |  |

## Myoma Drills

| Product                                                                             | Description | Dimension | Code      |                                                                                       |
|-------------------------------------------------------------------------------------|-------------|-----------|-----------|---------------------------------------------------------------------------------------|
|  | Myoma Drill | φ 5X330   | 221-53109 |  |
|                                                                                     |             | φ 5X420   | 221-54109 |                                                                                       |
|                                                                                     |             | φ 10X330  | 221-03109 |                                                                                       |
|                                                                                     |             | φ 10X420  | 221-04109 |                                                                                       |

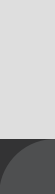
## Suction & Irrigation Apparatus

| Product                                                                             | Description            | Dimension | Code      |                                                                                     |
|-------------------------------------------------------------------------------------|------------------------|-----------|-----------|-------------------------------------------------------------------------------------|
|  | Suction and irrigation | φ 5X330   | 221-53114 |                                                                                     |
|  | Suction and irrigation | φ 5X330   | 221-53224 |  |
|                                                                                     |                        | φ 10X330  | 221-03224 |                                                                                     |

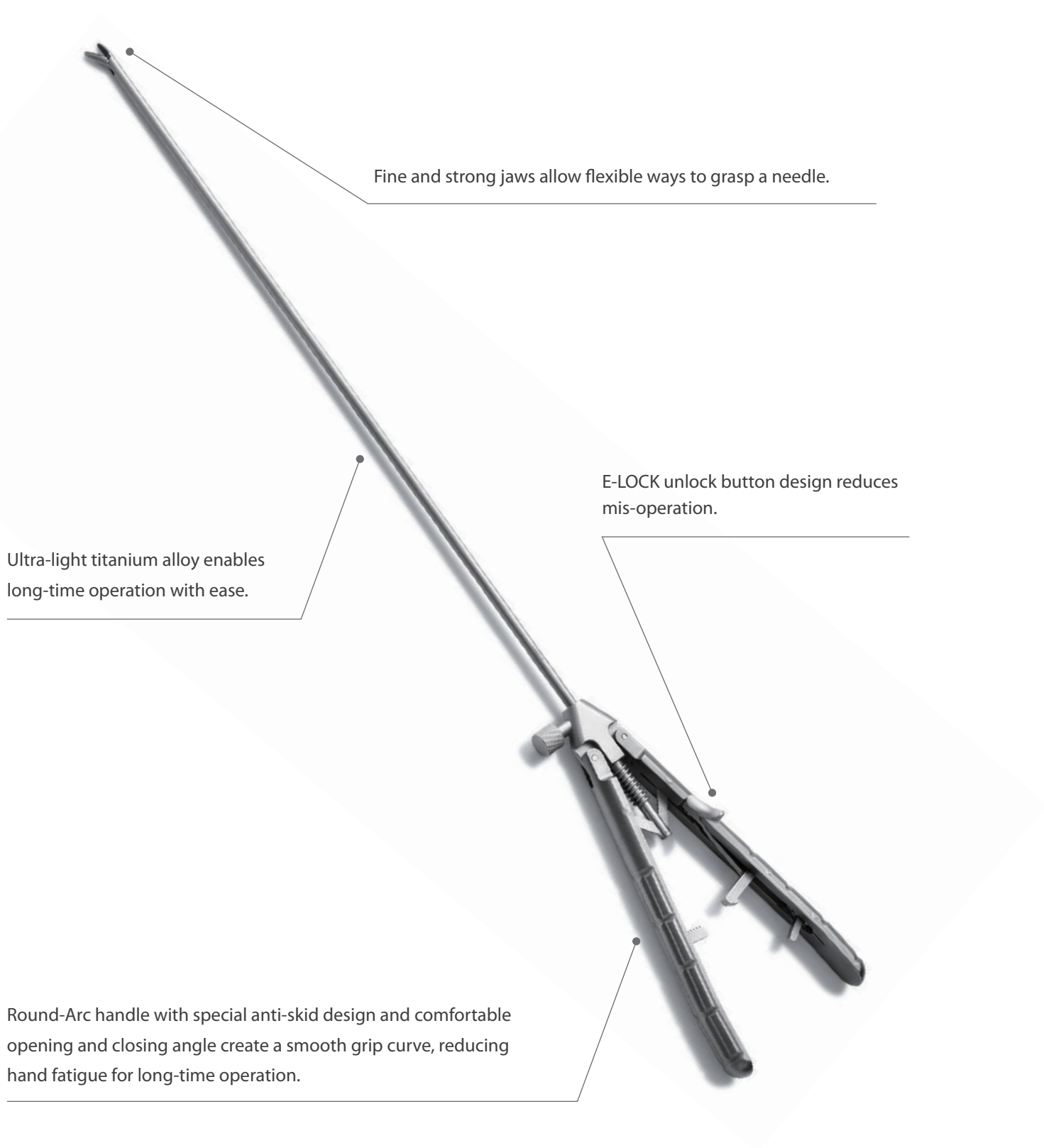
## Puncture Injection Needles



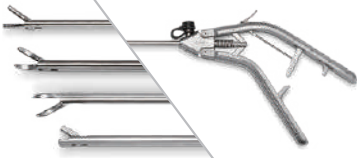
| Description                     | Pinhead | Dimension | Code      |                                                                                       |
|---------------------------------|---------|-----------|-----------|---------------------------------------------------------------------------------------|
| Puncture Injection Needle (7#)  | 0.7mm   | φ 5X330   | 221-53015 |                                                                                       |
| Puncture Injection Needle (9#)  | 0.9mm   | φ 5X330   | 221-53025 |                                                                                       |
| Puncture Injection Needle (13#) | 1.3mm   | φ 5X330   | 221-53035 |  |
| Puncture Injection Needle (16#) | 1.6mm   | φ 5X330   | 221-53055 |                                                                                       |
| Puncture Injection Needle (18#) | 1.8mm   | φ 5X330   | 221-53065 |                                                                                       |



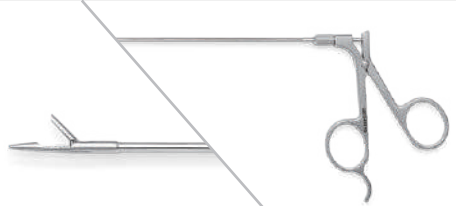
# Needle Holders



# Needle Holders

| Product                                                                             | Description                                          | Dimension | Code      |   |
|-------------------------------------------------------------------------------------|------------------------------------------------------|-----------|-----------|---|
|  | V Handle Straight Needle Holder                      | φ 5X330   | 221-56416 |   |
|                                                                                     | V Handle Left Curved Needle Holder                   | φ 5X330   | 221-56426 | 👍 |
|  | Pistol Handle Straight Needle Holder                 | φ 5X330   | 221-56516 |   |
|                                                                                     | Pistol Handle Left Curved Needle Holder              | φ 5X330   | 221-56526 |   |
|                                                                                     | Pistol Handle Right Curved Needle Holder             | φ 5X330   | 221-56536 |   |
|                                                                                     | Pistol Handle Needle Holder with Reposition Function | φ 5X330   | 221-56546 |   |
|  | O Handle Straight Needle Holder                      | φ 5X330   | 221-56816 |   |
|                                                                                     |                                                      | φ 5X450   | 221-56876 |   |
|                                                                                     | O Handle Left Curved Needle Holder                   | φ 5X330   | 221-56826 |   |
|                                                                                     |                                                      | φ 5X450   | 221-56886 | 👍 |
|                                                                                     | O Handle Right Curved Needle Holder                  | φ 5X330   | 221-56836 |   |
|                                                                                     | O Handle Needle Holder with Reposition Function      | φ 5X330   | 221-56846 |   |

# Suture Fascia Fix Forceps

| Product                                                                               | Description               | Dimension | Code      |   |
|---------------------------------------------------------------------------------------|---------------------------|-----------|-----------|---|
|  | Suture Fascia Fix Forceps | φ 3X200   | 221-32013 | 👍 |

# Knot Pushers

| Product                                                                               | Description | Note      | Dimension | Code      |   |
|---------------------------------------------------------------------------------------|-------------|-----------|-----------|-----------|---|
|  | Knot Pusher | Half Ring | φ 4X330   | 221-43019 | 👍 |
|  |             | Full Ring | φ 4X330   | 221-43029 |   |



## Reusable Electrode Surgical Instruments (ST)

(Scissors, Graspers, Dissectors, Forceps)

## Instructions for use

## STATEMENT

Hangzhou Mindray Medical Technology Co., Ltd. (hereinafter called Mindray) owns the intellectual property rights to this product and this manual. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden. This manual provides the instructions necessary to operate the product in accordance with its function and intended use. Observation of this manual is a prerequisite for proper performance and correct operation, and ensures patient and operator safety. Mindray is responsible for safety, reliability and performance of this product only in the condition that:

- This product is operated under strict observance of this manual.
- This product is not damaged by human factors. Human factors refer to unintentional falling, intentional damaging, etc.

In the event that it becomes necessary to return a unit to Mindray, please contact the Mindray Service Department. Please provide the model number, serial number, and a brief description of the reason for return. The customer is responsible for freight charges when this product is shipped to Mindray for service (including any relevant customs fees or other freight related charges).

For this operator's manual, the issued date is 2023-07 (version: 1.0)



Hangzhou Mindray Medical Technology Co., Ltd.  
Address: No.2 Fengxiang Road, Economic Development Zone, Tonglu,  
Hangzhou, Zhejiang 311508, China  
Tel: 086-571-58504222  
Fax: 086-571-58504300  
Website: www.mindray.com



Shanghai International Holding Corp. GmbH (Europe)  
Address: Elbestrasse 80, 20537 Hamburg, Germany  
Tel: 0049-40-2513175/2513174

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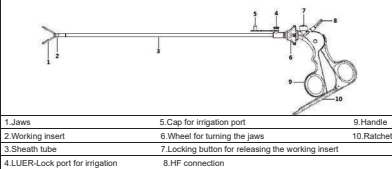
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## 1 General Description

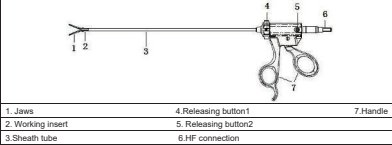
## 1.1 Components

## Components of Unipolar Instruments



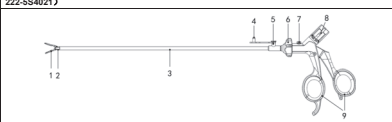
|                                  |                                                    |             |
|----------------------------------|----------------------------------------------------|-------------|
| 1. Jaws                          | 5. Cap for irrigation port                         | 9. Handle   |
| 2. Working insert                | 6. Wheel for turning the jaws                      | 10. Ratchet |
| 3. Sheath tube                   | 7. Locking button for releasing the working insert |             |
| 4. LUER-Lock port for irrigation | 8. HF connection                                   |             |

## Components of Bipolar Instruments (Applicable Models: 222-53111, 222-53121)



|                   |                      |           |
|-------------------|----------------------|-----------|
| 1. Jaws           | 4. Releasing button1 | 7. Handle |
| 2. Working insert | 5. Releasing button2 |           |
| 3. Sheath tube    | 6. HF connection     |           |

## Components of Bipolar Instruments (Applicable Models: 222-5S3011, 222-5S4011, 222-5S3021, 222-5S4021)



|                   |                                  |                                                    |
|-------------------|----------------------------------|----------------------------------------------------|
| 1. Jaws           | 4. Cap for irrigation port       | 7. Locking button for releasing the working insert |
| 2. Working insert | 5. LUER-Lock port for irrigation | 8. HF connection                                   |
| 3. Sheath tube    | 6. Wheel for turning the jaws    | 9. Handle                                          |

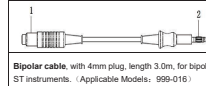
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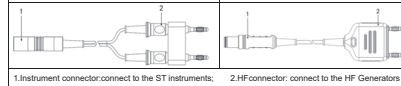
## Components of Accessories

**Mono-polar cable**, with 4mm plug, length 3.2m, for unipolar ST instruments.



**Bipolar cable**, with 4mm plug, length 3.0m, for bipolar ST instruments. (Applicable Models: 999-016)

**Bipolar cable**, with 4mm plug, length 3.2m, for bipolar ST instruments. (Applicable Models: 999-031)



1. Instrument connector connect to the ST instruments; 2. HF connector connect to the HF Generators.

## 1.2 Symbol Definitions

## Table 1 Symbol definitions

|  |                                                                                            |  |                                                     |  |                                                                                            |
|--|--------------------------------------------------------------------------------------------|--|-----------------------------------------------------|--|--------------------------------------------------------------------------------------------|
|  | Refer to instruction manual/booklet                                                        |  | Batch Code                                          |  | Temperature limit                                                                          |
|  | Caution                                                                                    |  | Latex-free                                          |  | Stacking limit by mass                                                                     |
|  | Type BF applied part                                                                       |  | This way up                                         |  | Keep away from sunlight                                                                    |
|  | Manufacturer                                                                               |  | Fragile, handle with care                           |  | Keep Dry                                                                                   |
|  | Atmospheric pressure                                                                       |  | Humidity limitation                                 |  | Unique Device Identification                                                               |
|  | Catalogue Number                                                                           |  | Authorized representative in the European Community |  | Separate collection for electrical and electronic equipment                                |
|  | The product conforms to the requirements of the EC Directive MDD(SM/CEC) on medical device |  | Medical Device                                      |  | Trademark of manufacture, authorized by Shenzhen Mindray Bio-Medical Electronics Co., Ltd. |

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## 1.3 Definition of Safety Notes

## Table 2 Definitions of safety notes

| Safety Notes | Meaning                                                                                                               |
|--------------|-----------------------------------------------------------------------------------------------------------------------|
|              | Read the statement below the symbol. The statement alerts you to an operating hazard that can cause personnel injury. |
|              | Read the statement below the symbol. The statement alerts you to possible damage to the device or other property.     |
|              | Read the statement below the symbol. The statement alerts you to information that requires your attention.            |

## 1.4 Intended Use

ST instruments are used to dissect and grasp or cut; ST curettes for dissection and preparation of soft tissue. ST instruments with a HF connection can also be used for coagulation of tissue or for the coagulation of minor hemorrhages. It is recommended to check the suitability of the products for the intended procedure prior to use.

## 1.5 Contraindications

No contraindications relating directly to the product are currently known. Use of ST instruments is contraindicated if, in the opinion of the responsible physician, the use of such an application would endanger the patient, e.g. due to the patient's general condition, or if the endoscopic method as such is contraindicated.

## 1.6 Specification

- Working parameter:
  - $\Phi 3.5 \times 200\text{mm}$ ,  $\Phi 3.5 \times 360\text{mm}$ ;
  - $\Phi 5 \times 300\text{mm}$ ,  $\Phi 5 \times 350\text{mm}$ ,  $\Phi 5 \times 360\text{mm}$ ,  $\Phi 5 \times 430\text{mm}$ ;
  - $\Phi 10 \times 330\text{mm}$ ,  $\Phi 10 \times 350\text{mm}$ ,  $\Phi 10 \times 430\text{mm}$ .
- Railed voltage: unipolar surgical instrument: 3000Vp; bipolar surgical instrument: 800Vp.

## 1.7 Safety Instructions

## WARNING

- Failure to observe and follow this instruction for use and the instruction manuals of products used in combination can result in injury to patients, users and third parties as well as damage to the product. Please read all relevant instructions carefully and always follow the instructions given precisely. Check the functioning of the products used in combination.
- There is a risk of injury if the insulation on HF generators is damaged or missing or if there is unintentional contact between the applied part and the patient. Do not use HF generators with damaged or missing insulation and make sure that the applied parts do not come into contact with conductive instruments, accessories and liquids. Never place the applied parts on the patient.
- Incorrectly assembled and damaged instruments can lead to injury to the patient. Instruments and all of the accessories used in combination with them must be checked immediately before and after every use to ensure that they are complete, free from damage, and in full working order and have no unintentional rough surfaces, sharp corners, burrs edges or projecting parts. Care must be taken not to leave missing or broken-off components inside the patient.
- Overloading the instrument by exerting too much force may cause the medical device to break, bend, and malfunction, and consequently injure the patient or user. Do not overload the instruments back to their original positions.

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- Incorrectly application of medical instruments poses a risk of injury for patients. Users of medical instruments must have an appropriate medical qualification and be acquainted with the application.
- During operation, the electrode jaw may be hot about 40°C-100°C. Maybe burn the patient.
- After coagulating, be sure to keep the jaw far away from patient to prevent high temperature harm.
- If the applied parts are used outside the field of vision there is a risk that tissue and accessories could be damaged unintentionally. Always hold the applied parts of the active electrode, laser and other instruments which transmit energy in a target-oriented manner in the field of vision during application.
- These instruments are not sterile when delivered. The use of non-sterile instruments poses a risk of infection for patient, users and third parties. Inspect instruments for visible contamination. Visible contamination is an indication that reprocessing has not been carried out or has been carried out incorrectly. Reprocess the instruments before initial use and before and after every subsequent use using validated procedures.
- ST instruments cannot be used in conjunction with oxygen rich environments. Sparks may be produced when HF generators and accessories are used, which can cause combustible or flammable liquids to ignite or explode. Make sure that combustible or flammable agents have evaporated before using HF generators and that no flammable gases are present.
- Use ST instruments only with HF generators that comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2 standards.

## CAUTION

- ST instruments with HF connections used in combination with HF units are intended for a recurring peak voltage of max. 3000Vp for unipolar instruments, 800Vp for bipolar instruments. Usage with device settings of over required voltage can lead to damage to the instrument (in accordance with IEC60601-2-2, 5th edition).

## 2 Disassembly and Assembly

## NOTE

- For safety reasons, handles with an HF connection can only be connected to insulated outer sheaths.

## 2.1 Disassembly of Unipolar Instruments

- Open handle completely. If necessary, unlock the locking mechanism on the handle.
- Press and hold the locking button (7) (do not turn).
- The handle is now opened completely in order to pull the sheath tube (3) out towards the front.
- To remove the working insert, hold the jaws (1) tightly and rotate the sheath tube (3) 1/4 turn.
- Pull out the working insert.

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## 2.2 Disassembly of Bipolar Instruments (Applicable Models: 222-53111, 222-53121)

- Press both release buttons (1) and (2) at the same time and pull the sheath tube (3) out of the handle.
- Hold the jaws (1), unscrew the working insert out of the sheath tube (3).
- Pull out the working insert.
- To open the jaws, hold the working insert on the joint sleeve and slide the rod towards the jaws.

## 2.3 Disassembly of Bipolar Instruments (Applicable Models: 222-5S3011, 222-5S4011, 222-5S3021, 222-5S4021)

- Press the button (1) with one hand, meanwhile, the other hand dematerializes the forceps casing and core (2) in the direction indicated by the arrow. The first step is finished (3).
- Continuing to the first step, seize the forceps casing (2) while using the other hand to pinch the end of forceps, rotate as picture shown (4), and pull it out of the casing. Disassembly is complete (5).

## 2.4 Assembly of Unipolar Instruments

- Insert the working insert (2) from the front into the sheath tube (3).
- Lock the working insert (2) by rotating 1/4 turn in the

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- bayonet mount on the sheath tube (3).
- Insert the sheath with closed jaws into the completely opened handle as far as it will go.
- Lock the sheath by completely closing the handle. Check that the instrument works properly.

## 2.5 Assembly of Bipolar Instruments (Applicable Models: 222-53111, 222-53121)

- To close the jaws, hold the working insert on the joint sleeve and pull the rod.
- Slide the working insert (2) into the sheath tube (3).
- Screw the working insert (2) on the joint sleeve as far as it will go.
- Press the releasing button (7) on the handle and slide the sheath tube as far as it will go and latch into the handle.

## 2.6 Assembly of Bipolar Instruments (Applicable Models: 222-5S3011, 222-5S4011, 222-5S3021, 222-5S4021)

- Insert the forceps core into its casing (1) towards the direction of the arrow, rotate the core to the end as indicated (2). The assembly of forceps core and its casing is complete.
- After that, place the handle upside down (as shown on the right), hold the front of the handle in one hand, insert the forceps core and its casing in the other hand (3) until a "click" is heard. The assembly is finished.

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## 3 General Instruction for Use

- Make sure the product has been cleaned and sterilized prior to the first use and after every subsequent use.
- Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.
- Using a standard endoscopic technique, close the jaw and insert the instrument through an appropriately sized cannula.
- To rotate the wheel, turn the jaw to desired location.
- For instruments with ratchet, position tissue inside the jaws and squeeze handle to desired clamping tightness. Different closure degrees have different locking forces. Please operate as noted.
- Close the jaws before attempting to withdraw instruments through the cannula. Visualize fully to avoid trapping tissue between the jaws of the instrument and causing inadvertent damage. Pull the instrument straight out through the cannula, avoiding lateral pressure that damage the jaw.
- Use the right cable to connect ST instrument to the HF generator before the procedure. Connect the instrument connector of cable to the HF connection of ST instrument (see 1.1 components of accessories). Make sure that mono-polar cables are used for unipolar instruments and bipolar cables are used for bipolar instruments.

## 4 Reprocessing

## WARNING

- Incorrectly reprocessed medical devices pose patients, users and third parties to a risk of infection as well as the risk that the medical device may malfunction.

## CAUTION

- When preparing and using the solutions, follow the chemical manufacturer's specifications, paying close attention to proper concentration, exposure time and service life. Prolonged immersion and incorrect concentration may result in damage. Bear in mind the microbiological range of action of the chemical used.
- The use of chemical which has not been approved by Mindray may cause damage to the medical devices. Only use chemicals approved for reprocessing.
- National laws and regulations must be observed.

## NOTE

- The service life of the products is largely determined by wear, reprocessing methods, the chemicals used and any damage resulting from use.

## 4.1 Disassembly

Prior to cleaning and disinfection, the medical device must be separated into individual components as much as possible and the jaws of the forceps insert must be opened. (See chapter 2 for details)

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## 4.2 Preparation for Cleaning and Disinfection

Heavy soiling, corrosive solutions and pharmaceuticals must be removed from the medical device immediately after use. To this end, pre-clean the medical device by wiping down and rinsing, for example. As a general rule, we recommend manual pre-cleaning under cold running water. A preliminary cleaning of coagulation instruments may be necessary before disposal. In order to remove incrustations, we recommend using a surgical pad soaked in 3% hydrogen peroxide.

## 4.3 Manual Pre-cleaning

## 4.3.1 Brushing the Surfaces

Heavy soiling must be removed from the surfaces of the individual components by cleaning under cold running water with the aid of a brush or sponge.

## 4.3.2 Brushing the Lumina

In order to remove all visible contamination, the lumens of the outer sheath must be pre-cleaned under cold running water with the aid of a suitable brush.

## 4.4 Manual cleaning

The individual components must be completely immersed in a cleaning solution. Through opening the jaws at the forceps insert and filling the lumina in a targeted manner, it must be ensured even surfaces with restricted access are covered and no air bubbles are present. After the necessary exposure time, clean the instrument mechanically with the aid of a brush or sponge. Finally, it must be rinsed with cold running water to ensure neutralization.

## 4.5 Manual disinfection

The individual components must be completely immersed in a disinfection solution. Through opening the jaws at the forceps insert and filling the lumina in a targeted manner, it must be ensured even surfaces with restricted access are covered and no air bubbles are present. Following the exposure time, the medical devices must be rinsed several times with completely demineralized water or microbiologically pure, sterile water in order to remove all chemical residues. Finally, all surfaces, joints, openings, channels and lumina are dried completely with sterile compressed air.

## 4.6 Machine Cleaning and Disinfection

## 4.6.1 Connecting

In order to ensure effective machine cleaning and disinfection, the outer sheath must be connected up to the washer and disinfectant via the LUER-connector.

## 4.6.2 Disinfection

Thermal disinfection is preferred. The relevant national requirements and the A<sub>0</sub> value must be taken into account when using the method.

The selection of a suitable slide-in tray or instrument holder, which should ensure that the medical device is thoroughly rinsed out or tough, must take into consultation with the manufacturer of the device.

## NOTE

- If necessary, the instrument must be dried off afterwards by hand.

## 4.7 Assembly, Inspection and Care

The cleaned and disinfected medical device must be visually inspected for cleanliness, completeness, damage and dryness.

- If residues or contamination are still present, the medical device must be manually cleaned and subjected to a full cleaning and disinfection procedure once more.
- Damaged or corroded medical devices must be withdrawn from use.
- Disassembled medical devices must be assembled.
- Afterwards, a functional check must be carried out.

## 4.8 Sterilization

We recommend using the moist heat. The sterilization parameter is listed below:

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| Reusable Electrode Surgical Instruments (ST) |                  |             |                  |           |
|----------------------------------------------|------------------|-------------|------------------|-----------|
| Sterilization Method                         | Product Category | Temperature | The Minimum Time | Pressure  |
| Mold heat—Gravity Displacement Autoclave     | Appliance        | 121°C       | 30 Min           | 102.9 Kpa |
| Mold heat—Pre Vacuum Process                 | Appliance        | 132-134°C   | 4 Min            | 206.8 Kpa |

5 Directive Compliance

This medical device bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.

6 Storage conditions

Store in controlled environment, which should keep away from the sun, rats, fire, insects and caustic gas, as well as with good ventilation.

7 Transportation conditions

Temperature range: -20℃～-50℃; relative humidity range: 10%～80%; atmospheric pressure: 500hpa-1060hpa.

8 Operating conditions

Temperature range: 10℃～-40℃; relative humidity range: 30%～80%; atmospheric pressure: 700hpa-1060hpa.

9 Disposal

To dispose of ST instruments, no special measures are necessary. National regulations/laws must be observed.

10 Product Model

| Product model (T for ratchet instruments and S for non-ratchet instruments) |            |            |            |            |
|-----------------------------------------------------------------------------|------------|------------|------------|------------|
| Unipolar Instruments                                                        |            |            |            |            |
| 222-050123                                                                  | 222-351013 | 222-071013 | 222-053403 | 222-073403 |
| 222-054123                                                                  | 222-353013 | 222-073013 | 222-054403 | 222-074403 |
| 222-050133                                                                  | 222-052013 | 222-072013 | 222-053413 | 222-073413 |
| 222-351212                                                                  | 222-053013 | 222-073013 | 222-053423 | 222-073423 |
| 222-050213                                                                  | 222-054013 | 222-072113 | 222-052433 | 222-074433 |
| 222-050313                                                                  | 222-351013 | 222-071013 | 222-053433 | 222-074433 |
| 222-054213                                                                  | 222-351023 | 222-074213 | 222-054433 | 222-074433 |
| 222-050223                                                                  | 222-353023 | 222-072023 | 222-053433 | 222-074433 |
| 222-050323                                                                  | 222-052023 | 222-072023 | 222-054433 | 222-074433 |
| 222-054223                                                                  | 222-053023 | 222-073023 | 222-052433 | 222-074433 |
| 222-351233                                                                  | 222-054023 | 222-074023 | 222-053443 | 222-074443 |
| 222-050233                                                                  | 222-351023 | 222-071023 | 222-050453 | 222-074453 |
| 222-050333                                                                  | 222-052033 | 222-072033 | 222-053453 | 222-074453 |
| 222-054233                                                                  | 222-053033 | 222-073033 | 222-054453 | 222-074453 |
| 222-054233                                                                  | 222-054033 | 222-074033 | 222-055463 | 222-074463 |
| 222-351233                                                                  | 222-055043 | 222-075043 | 222-056463 | 222-074463 |
| 222-050233                                                                  | 222-056043 | 222-076043 | 222-057463 | 222-074463 |
| 222-050333                                                                  | 222-057043 | 222-077043 | 222-058463 | 222-074463 |
| 222-054233                                                                  | 222-058043 | 222-078043 | 222-059463 | 222-074463 |
| 222-351233                                                                  | 222-059043 | 222-079043 | 222-060463 | 222-074463 |
| 222-050233                                                                  | 222-060043 | 222-080043 | 222-061463 | 222-074463 |
| 222-050333                                                                  | 222-061043 | 222-081043 | 222-062463 | 222-074463 |
| 222-054233                                                                  | 222-062043 | 222-082043 | 222-063463 | 222-074463 |
| 222-351233                                                                  | 222-063043 | 222-083043 | 222-064463 | 222-074463 |
| 222-050233                                                                  | 222-064043 | 222-084043 | 222-065463 | 222-074463 |
| 222-050333                                                                  | 222-065043 | 222-085043 | 222-066463 | 222-074463 |
| 222-054233                                                                  | 222-066043 | 222-086043 | 222-067463 | 222-074463 |
| 222-351233                                                                  | 222-067043 | 222-087043 | 222-068463 | 222-074463 |
| 222-050233                                                                  | 222-068043 | 222-088043 | 222-069463 | 222-074463 |
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| 222-351233                                                                  | 222-071043 | 222-091043 | 222-072463 | 222-074463 |
| 222-050233                                                                  | 222-072043 | 222-092043 | 222-073463 | 222-074463 |
| 222-050333                                                                  | 222-073043 | 222-093043 | 222-074463 | 222-074463 |
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| 222-351233                                                                  | 222-143043 | 222-163043 | 222-144463 | 222-074463 |
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| 222-050333                                                                  | 222-145043 | 222-165043 | 222-146463 | 222-074463 |
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| 222-050233                                                                  | 222-152043 | 222-172043 | 222-153463 | 222-074463 |
| 222-050333                                                                  | 222-153043 | 222-173043 | 222-154463 | 222-074463 |
| 222-054233                                                                  | 222-154043 | 222-174043 | 222-155463 | 222-074463 |
| 222-351233                                                                  | 222-155043 | 222-175043 | 222-156463 | 222-074463 |
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| 222-050333                                                                  | 222-157043 | 222-177043 | 222-158463 | 222-074463 |
| 222-054233                                                                  | 222-158043 | 222-178043 | 222-159463 | 222-074463 |
| 222-351233                                                                  | 222-159043 | 222-179043 | 222-160463 | 222-074463 |
| 222-050233                                                                  | 222-160043 | 222-180043 | 222-161463 | 222-074463 |
| 222-050333                                                                  | 222-161043 | 222-181043 | 222-162463 | 222-074463 |
| 222-054233                                                                  | 222-162043 | 222-182043 | 222-163463 | 222-074463 |
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| 222-050233                                                                  | 222-164043 | 222-184043 | 222-165463 | 222-074463 |
| 222-050333                                                                  | 222-165043 | 222-185043 | 222-166463 | 222-074463 |
| 222-054233                                                                  | 222-166043 | 222-186043 | 222-167463 | 222-074463 |
| 222-351233                                                                  | 222-167043 | 222-187043 | 222-168463 | 222-074463 |
| 222-050233                                                                  | 222-168043 | 222-188043 | 222-169463 | 222-074463 |
| 222-050333                                                                  | 222-169043 | 222-189043 | 222-170463 | 222-074463 |
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| 222-050233                                                                  | 222-180043 | 222-200043 | 222-181463 | 222-074463 |
| 222-050333                                                                  | 222-181043 | 222-201043 | 222-182463 | 222-074463 |
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| 222-050333                                                                  | 222-189043 | 222-209043 | 222-190463 | 222-074463 |
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| 222-351233                                                                  | 222-195043 | 222-215043 | 222-196463 | 222-074463 |
| 222-050233</                                                                |            |            |            |            |





# Reusable Laparoscopic Instruments

## Instruction Manual

### Statement

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Mindray shall be responsible for the safety, reliability and performance of the product provided that the following conditions are met:

- This product is used in accordance with the Instruction Manual.
- Product damage caused by non-human factors (human factors refer to accidental falls, deliberate damage, etc.).

If you really need to return the product to Mindray, please contact the after-sales service department of Mindray, inform the product model and serial number, and briefly explain the reason. The "three guarantees" of the instrument and after-sales service will be implemented according to the product "three guarantees" and after-sales service contract agreed and signed between the distribution unit and the manufacturing company.

After-sales service unit: Hangzhou Mindray Medical Technology Co., Ltd.  
After-sales unit address: No.2 Fengxiang Road, Tonglu Economic Development Zone, Tonglu County, Hangzhou City  
After-sales unit tel: 0571-58504222

Compilation date: 2024-11



Hangzhou Mindray Medical Technology Co., Ltd.

Address: No.2 Fengxiang Road, Economic Development Zone, Tonglu, Hangzhou, Zhejiang 311508, China

Tel: 086-571-58504222

Fax: 086-571-58504300

Website: www.mindray.com



Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffelstrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175/2513174

Mindray

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### 1. Product Structure

The instrument consists of Endo Applier for Clips (Endo Applier for Titanium Clips, clip applier), needle holder, Suture Fascia Fix Forceps, trocar, converter, Puncture Injection Needle, Suction and irrigation, Finger Retractor, ENDO-Retractor, Myoma Drill, veress needle and knot pusher, with seals as auxiliary components.

| Collectively                    | Product Name                                               | Specification | Product Model |
|---------------------------------|------------------------------------------------------------|---------------|---------------|
| Endo Applier for Titanium Clips | Endo Applier for Small Titanium Clip, Single action        | φ5X330        | 221-55116     |
|                                 | Endo Applier for Medium Titanium Clip, Single action       | φ10X330       | 221-05126     |
|                                 | Endo Applier for Medium Large Titanium Clip, Single action | φ10X330       | 221-05136     |
|                                 | Endo Applier for Large Titanium Clip, single action        | φ10X330       | 221-05146     |
| Clip applier                    | Endo Applier for Medium Large Hemolock Clip                | φ5X330        | 221-55636     |
|                                 | Endo Applier for Large Hemolock Clip                       | φ10X330       | 221-05646     |
|                                 | Endo Applier for Extra Large Hemolock Clip                 | φ10X330       | 221-05656     |
| Needle holder                   | O Handle Straight Needle Holder                            | φ5X330        | 221-56816     |
|                                 | O Handle Straight Needle Holder                            | φ5X450        | 221-56876     |
|                                 | O Handle Left Curved Needle Holder                         | φ5X330        | 221-56826     |
|                                 | O Handle Left Curved Needle Holder                         | φ5X450        | 221-56886     |
|                                 | O Handle Right Curved Needle Holder                        | φ5X330        | 221-56836     |
|                                 | O Handle Needle Holder with Reposition Function            | φ5X330        | 221-56846     |
|                                 | Pistol Handle Straight Needle Holder                       | φ5X330        | 221-56516     |
|                                 | Pistol Handle Left Curved Needle Holder                    | φ5X330        | 221-56526     |
|                                 | Pistol Handle Right Curved Needle Holder                   | φ5X330        | 221-56536     |
|                                 | Pistol Handle Needle Holder with Reposition Function       | φ5X330        | 221-56546     |
|                                 | V Handle Straight Needle Holder                            | φ5X330        | 221-56416     |
|                                 | V Handle Left Curved Needle Holder                         | φ5X330        | 221-56426     |
| Suture Fascia Fix Forceps       | Suture Fascia Fix Forceps                                  | φ3X200        | 221-32013     |
| Trocar                          | Trocar                                                     | φ5X95         | 221-51155     |
|                                 | Trocar                                                     | φ10X95        | 221-01155     |
|                                 | Trocar                                                     | φ12X95        | 221-81155     |
|                                 | Trocar                                                     | φ5X150        | 221-53155     |
|                                 | Trocar                                                     | φ10X150       | 221-03155     |
|                                 | Trocar                                                     | φ12X150       | 221-83155     |
|                                 | Trocar                                                     | φ5X95         | 221-51255     |
|                                 | Trocar                                                     | φ10X95        | 221-01255     |
|                                 | Trocar                                                     | φ12X95        | 221-81255     |
|                                 | Trocar                                                     | φ5X150        | 221-53255     |
|                                 | Trocar                                                     | φ10X150       | 221-03255     |
|                                 | Trocar                                                     | φ12X150       | 221-83255     |
|                                 | Trocar                                                     | φ5X95         | 221-51165     |
|                                 | Trocar                                                     | φ10X95        | 221-01165     |
|                                 | Trocar                                                     | φ12X95        | 221-81165     |

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|                           |                                 |          |           |
|---------------------------|---------------------------------|----------|-----------|
| converter                 | Trocar                          | φ5X95    | 221-51265 |
|                           | Trocar                          | φ10X95   | 221-01265 |
|                           | Trocar                          | φ12X95   | 221-81265 |
|                           | Reducer Sleeve                  | φ10-φ5   | 221-01785 |
|                           | Reducer Sleeve                  | φ12-φ5   | 221-81785 |
|                           | Reducer                         | φ10-φ5   | 221-00715 |
|                           | Reducer                         | φ10-φ5   | 221-00725 |
| Puncture Injection Needle | Reducer                         | φ12-φ5   | 221-80725 |
|                           | Puncture Injection Needle (7#)  | φ5X330   | 221-53015 |
|                           | Puncture Injection Needle (9#)  | φ5X330   | 221-53025 |
|                           | Puncture Injection Needle (12#) | φ5X330   | 221-53035 |
|                           | Puncture Injection Needle (15#) | φ5X330   | 221-53055 |
| Suction and irrigation    | Puncture Injection Needle (18#) | φ5X330   | 221-53065 |
|                           | Suction and irrigation          | φ5X330   | 221-53114 |
|                           | Suction and irrigation          | φ5X330   | 221-53224 |
|                           | Suction and irrigation          | φ10X330  | 221-03224 |
| Finger Retractor          | Three Finger Retractor          | φ5X330   | 221-55923 |
|                           | Five Finger Retractor           | φ10X330  | 221-05923 |
| ENDO-Retractor            | ENDO-Retractor                  | φ5X360   | 221-53013 |
|                           | ENDO-Retractor                  | φ5X360   | 221-53023 |
| Myoma Drill               | Myoma Drill                     | φ5X330   | 221-53109 |
|                           | Myoma Drill                     | φ5X420   | 221-54109 |
|                           | Myoma Drill                     | φ10X330  | 221-03109 |
|                           | Myoma Drill                     | φ10X420  | 221-04109 |
|                           | Myoma Drill                     | φ2X120   | 221-21127 |
| Veress Needle             | Veress Needle                   | φ2,7X150 | 221-27157 |
|                           | Veress Needle                   | φ4X330   | 221-43019 |
| Knot Pusher               | Knot Pusher                     | φ4X330   | 221-43029 |
|                           | Knot Pusher                     | φ5       | 221-50925 |
| Sealing Cap               | Sealing Cap                     | φ10      | 221-00925 |
|                           | Sealing Cap                     | φ12      | 221-80925 |

### 2. Intend Use

For Suction and Irrigation Tube Set: It is used in the laparoscopic surgery to rinse the tissues, organs and suck away waste liquid.

For Trocar: It is used in clinical laparoscopic surgery in the hospital to establish access to the abdominal cavity for the instrument.

For Veress Needle: It is intended to establish pneumoperitoneum prior to trocar and cannula insertion in laparoscopic procedures by insufflations with carbon dioxide through percutaneous insertion.

For Needle Holder: It is intended to be used to place sutures in endoscopic surgery using suture material suitable for size of the needle holder.

For Endo Applier for Clips: Endoscopic for ligating and marking vessels and tubular structures whenever titanium clips are used/indicated.

For Puncture Injection Needle: Reusable surgically invasive device for temporary use. It is inserted via a trocar sleeve.

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For Suture Fascia Fix Forceps: It is intended to be used to close the incision in the abdominal wall during surgery.

For ENDO-Retractor: ENDO-Retractors are designed to support and retract the liver during laparoscopic upper abdominal surgery.

For Finger Retractor: It is intended to be used to detach the organs and expose the surgical field during surgery.

For Knot Pusher: It is intended to be used to push and tighten the knot during surgery.

For Myoma Drill: It is intended to be used to fix and pull uterine fibroids during surgery.

### 3. Component Specification

For detailed component model and specification, please refer to the component label on the product component package.



- Please read this instruction manual carefully before using the product;
- Any violation or deviation from the manual could cause harm to the patient;
- The instrument should only be used by licensed physicians and medical professionals trained to operate it.
- The instrument must not be under pressure, overlapped, impacted, or bumped, so as to prevent deformation and damage.
- Before each use, the instrument inserted into the human body must be checked for rough surfaces, sharp edges or protrusions that could cause injury.



- The product has limited pressure bearing capacity and excessive application of force can result in breakage or impaired functionality of the device and endanger the patient.

### NOTE

- After one year of use of the instrument, it is suggested that the instrument have a comprehensive inspection and maintenance by the manufacturer. If the instrument is found aged to the extent that it cannot be used, necessary measures can be taken to repair it, or just scrap it, so as to prevent the instrument from malfunctioning during the operation and endangering the patient.
- After the instrument is scrapped, it should be disposed of according to the disposal method for hospital medical waste to avoid pollution to the environment.
- The part of the needle holder that will be in contact with the patient is made of metal, and its surface material is consistent with the internal material.

### 4. Instructions for Use

- Make sure the product has been cleaned and sterilized prior to the first use and after every subsequent use.

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- Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted.

### 5. Schematic Diagram

- Needle holder

Note: There are many types of needle holder, which can be distinguished by the tip and handle

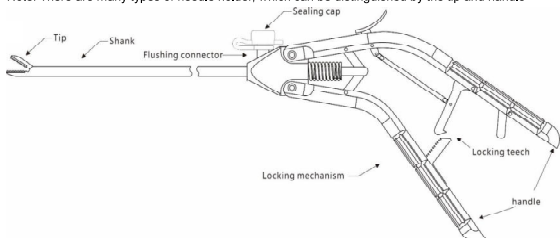


Table 1 Diagram of tip shape of needle holder

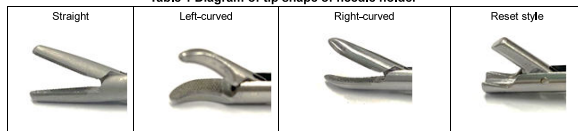
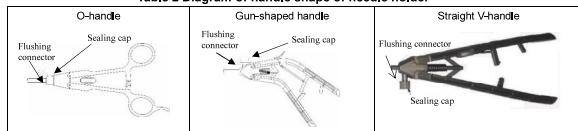


Table 2 Diagram of handle shape of needle holder



- Endo Applier for Titanium Clips and clip applier

Note: The Endo Applier for Titanium Clips and clip applier can be distinguished by the tip and handle

Table 3 Diagram of Endo applier for titanium clips

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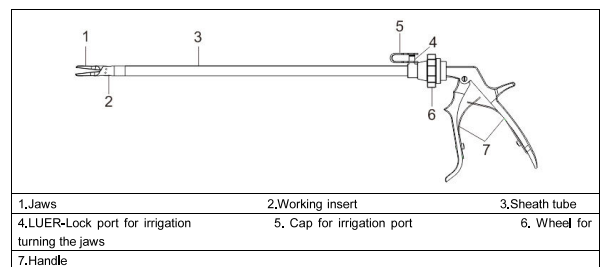


Table 4 Diagram of Clip applier

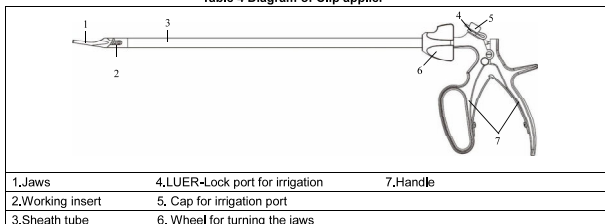
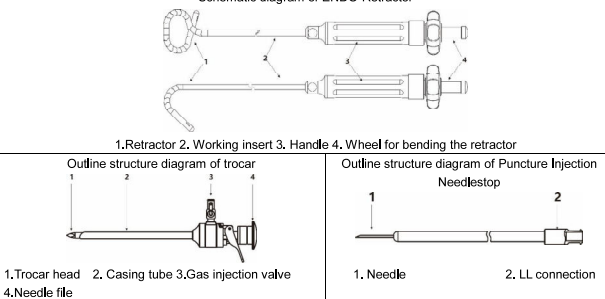


Table 5 Schematic diagram of other instruments

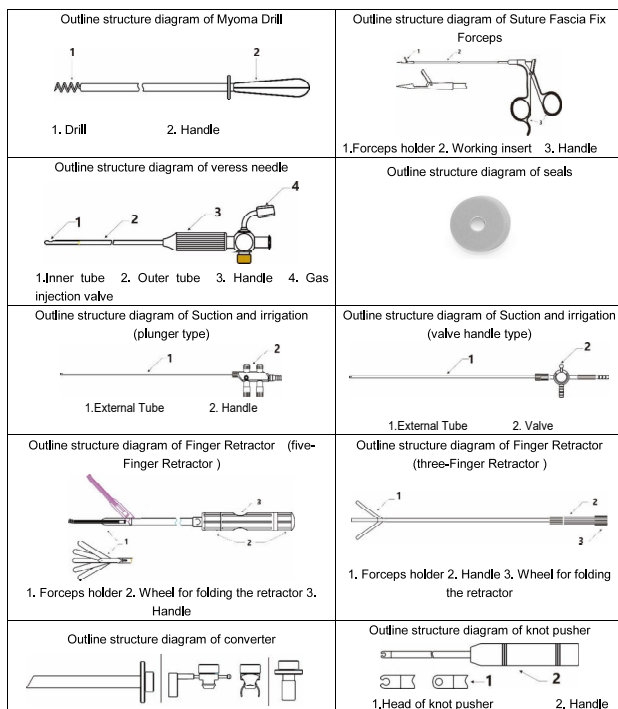
Schematic diagram of ENDO-Retractor



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### 6. Disassembly and Assembly

Before cleaning and sterilization, check and confirm that the instrument is in good condition, and then disassemble the instrument. If some instruments are directly cleaned and sterilized without disassembly, the effect is not good.

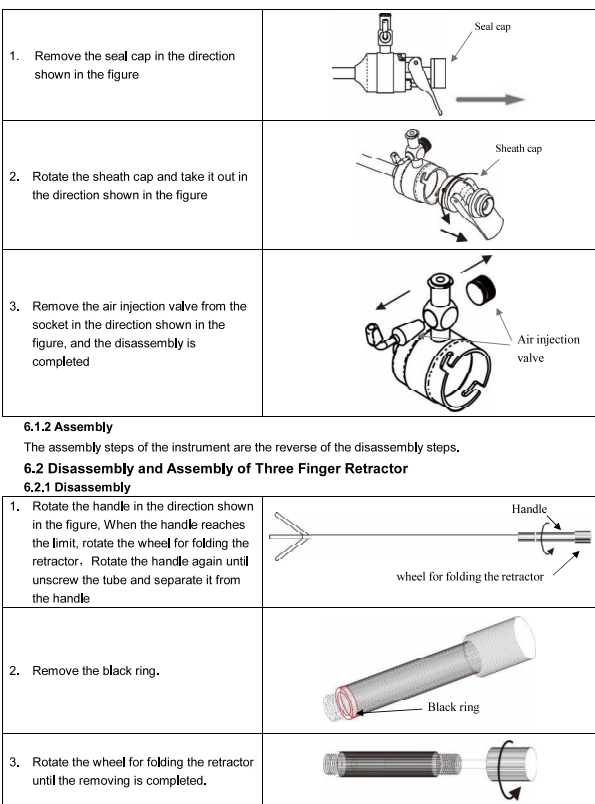
#### 6.1 Disassembly and assembly of trocars

##### 6.1.1 Disassembly:

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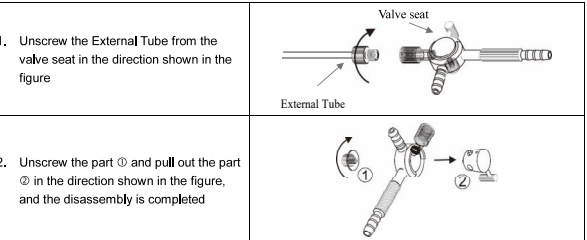
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#### 6.3 Disassembly and Assembly of Suction and irrigation (Valve Handle Type)

##### 6.3.1 Disassembly

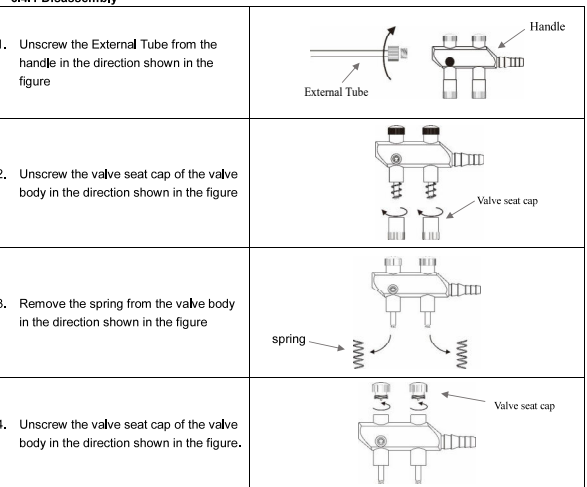


##### 6.3.2 Assembly

The assembly steps of the instrument are the reverse of the disassembly steps.

#### 6.4 Disassembly and Assembly of Suction and irrigation (Plunger Type)

##### 6.4.1 Disassembly



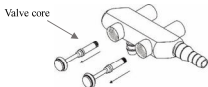
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5. Take out the valve core from the valve body, and the disassembly is completed



#### 6.4.2 Assembly

The assembly steps of the instrument are the reverse of the disassembly steps.

#### 6.5 Disassembly and Assembly of Other Instruments

Instruments with flushable connectors, such as needle holder, clip applicator, clip applier, ENDO-Retractor, etc., can be cleaned through the flushing channel without disassembly.

The remaining instruments, such as trocar needle, seal, veress needle, converter, knot pusher, fibroids drill, Suture Fascia Fix Forceps, etc., can be cleaned directly

### 7. Cleaning and Sterilization

Instruments are reusable products and can be cleaned and sterilized as follows. Cleaning and sterilization methods need to be verified by the using unit.

#### 7.1 Cleaning

- 1) Rinse the product with sufficient running water to remove residues such as blood, mucus and protein, and dry with a lint-free cloth;
- 2) The detachable parts need to be disassembled for cleaning;
- 3) Make an enzymatic cleaner solution in warm water (38°C -48°C) according to the manufacturer's instruction;
- 4) Soak the components in the soft enzymatic cleaner solution for 10 minutes;
- 5) Rinse the components in warm water and remove scaling and resistant dead cells from all surfaces with the soft enzymatic cleaner and a soft brush;
- 6) Clean the internal cavity and guide slot with an appropriate brush or cleaning spray gun (10 minutes);
- 7) Rinse off all detergent residues with pure water;
- 8) Visually inspect the components to ensure they are completely and thoroughly cleaned. Repeat steps 4) to 7) if residual and visible contamination exists;
- 9) Drying: wipe dry with clean gauze, and blow dry with clean compressed air for instruments with lumen, and then dry them in the oven at 60°C for 30 minutes.

#### 7.2 Steam sterilization

Mindray has verified the following parameters:

| Sterilization method             | Item category | Temperature | Minimum time required | Pressure  |
|----------------------------------|---------------|-------------|-----------------------|-----------|
| Steam sterilization - forevacuum | Instrument    | 132~134°C   | 4 Min                 | 205.8 kPa |

For the loading method and selection of sterilization procedures for high temperature steam sterilization, please refer to the operation instructions of the corresponding sterilizer. As the selected sterilizer and its operating conditions may affect the final sterilization effect, the sterilization process should be re-confirmed and monitored before sterilization according to relevant international standards (such as ISO 17665), national standards or hospital sterilization management practices for high temperature steam sterilization.

### 8. Maintenance

The product should be adequately and regularly maintained to avoid accidents and damage caused by aging and wear. The functional security and operational security of the product must be checked and confirmed by experts. The interval for this check depends on the number of uses, and should not be less than once a year.

### 9. Contraindications

Coagulation dysfunction, pregnancy, cardiopulmonary dysfunction.

### 10.Storage conditions

Store in controlled environment, which should keep away from the sun, rats, fire, insects and caustic gas, as well as with good ventilation.

### 11.Transportation conditions

Temperature range: -20°C ~ 50°C; relative humidity range: 10% ~ 80%; atmospheric pressure: 500hpa-1060hpa.

### 12.Operating conditions

Temperature range: 10°C ~ 40°C; relative humidity range: 30% ~ 80%; atmospheric pressure: 700hpa-1060hpa.

### 13. Production Date: see label.

### 14. Service Life

Times of reuse: 200 times;

### 15. Abandonment

The instrument must be disposed of in accordance with local regulations or the hospital's waste disposal regulations when it reaches its expiration date. Please clean and disinfect it before discarding.

## 16. Symbol Description

Table 6 Symbol Description

| Symbol | Meaning                                                                                                                                                                                        |
|--------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|        | Prompt the operator to follow the instructions under the symbol, otherwise personal injury may result.                                                                                         |
|        | Prompt the operator to follow the instructions under the symbol, otherwise may cause product failure, damage or affect the test results.                                                       |
|        | Prompt the operator to follow the instructions under the symbol, emphasizing the important information from the operation steps or the content that requires the operator's special attention. |

Table 7 Description of Symbols Used in Manuals and Labels

|        |                                                                                                               |  |                              |  |                                                                                            |
|--------|---------------------------------------------------------------------------------------------------------------|--|------------------------------|--|--------------------------------------------------------------------------------------------|
|        | Refer to instruction manual/booklet                                                                           |  | Catalogue Number             |  | Humidity limitation                                                                        |
| (Blue) |                                                                                                               |  |                              |  |                                                                                            |
|        | Atmospheric pressure limitation                                                                               |  | Batch No.                    |  | Temperature limit                                                                          |
|        | Avoid rain                                                                                                    |  | Avoid sun exposure           |  | Fragile, handle with care                                                                  |
|        | Manufacturer                                                                                                  |  | Stacking limit by mass       |  | This way up                                                                                |
|        | Medical Device                                                                                                |  | Unique Device Identification |  | Authorized representative in the European Community                                        |
|        | Labelling for Class I products. Developed and marketed in compliance with medical device directive 93/42/EEC. |  |                              |  | Trademark of manufacture, authorized by Shenzhen Mindray Bio-Medical Electronics Co., Ltd. |