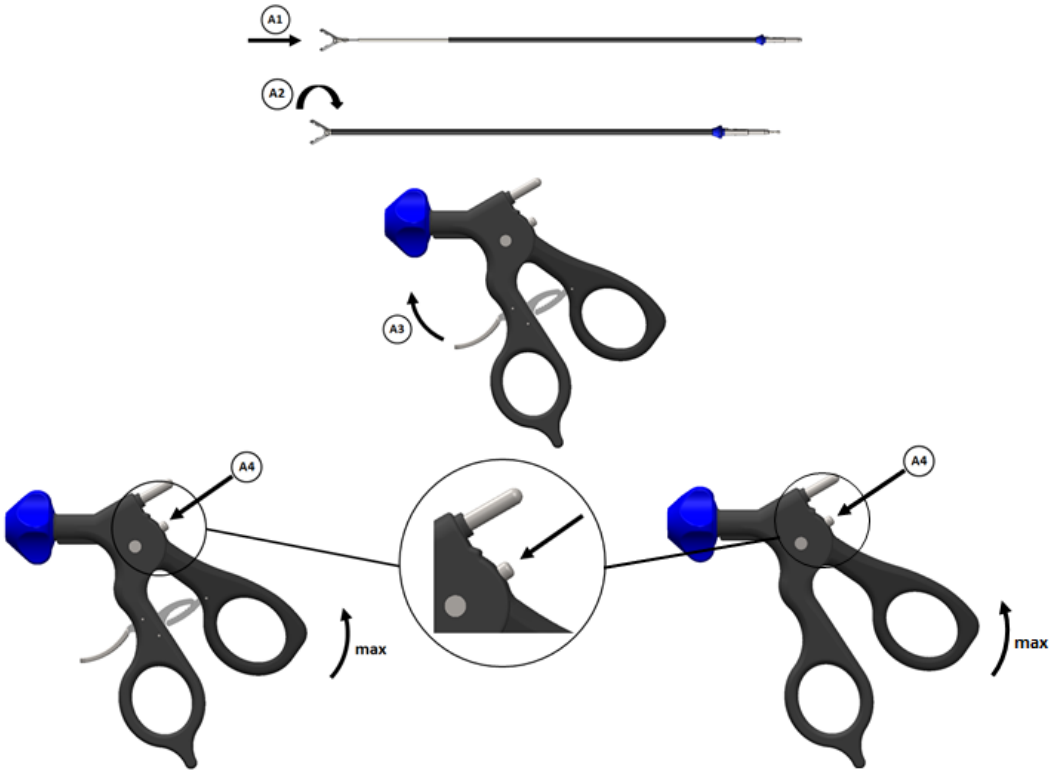
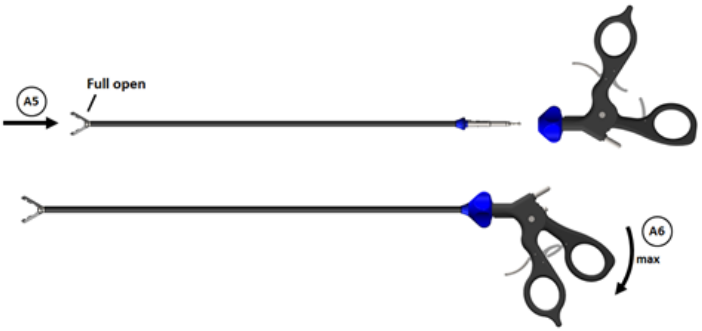
ASSEMBLY ORDER



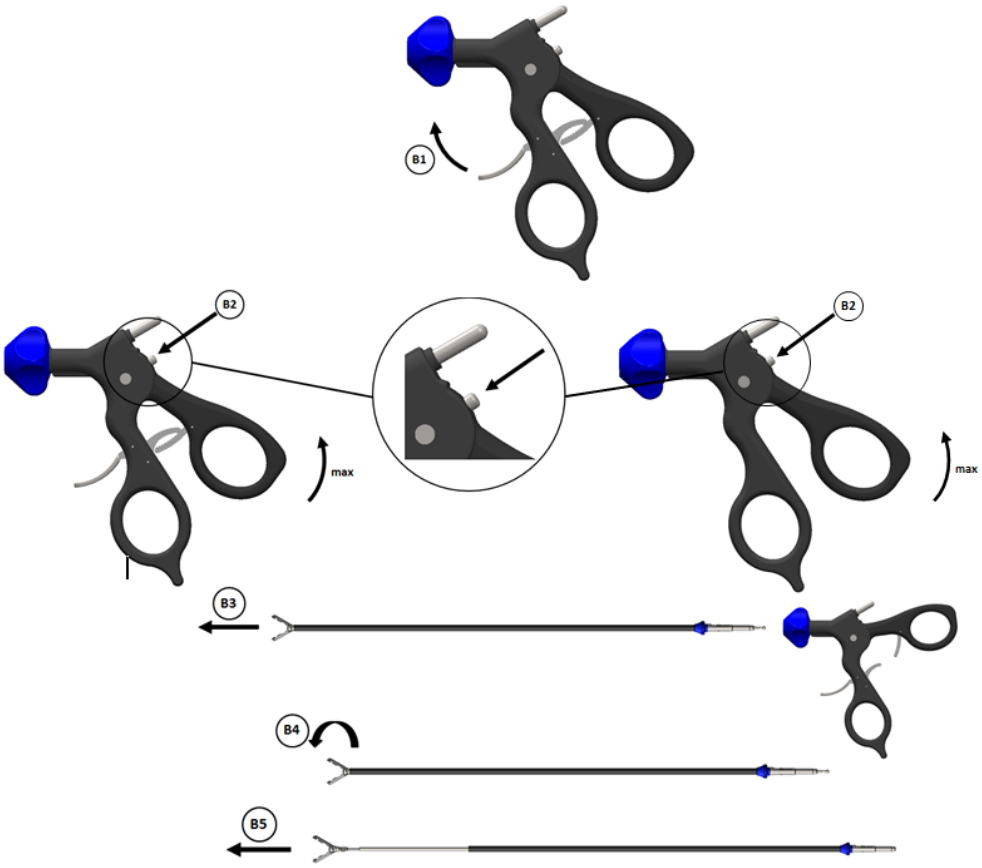
Instructions for use

EndoLine
Laparoscopic Instruments



REF **ELI-xxxxxx**

DISASSEMBLY ORDER



Explanation of symbols

 Caution

 Manufacturer

 Catalogue number

 Batch code

 Consult instruction for use

 Temperature limits

 93/42/EEC appropriateness according to this directive

Intended use

This device is intended for medical use, in minimally invasive abdominal surgery.

The instruments can be used to grasp, cut and / or manipulate soft tissue if deemed appropriate by the surgeon. In electrosurgical procedures, the scissors and forceps are capable of coagulating tissue if deemed necessary and appropriate by the surgeon.

It is up to the physician to decide about the selection of what type and size of instrument to use.

Intended user

This product may only be used by experienced medical staff skilled in endoscopic applications.

Contraindications

Absolute contraindications:

» Severe heart disease.

» Hemorrhage.

» Bowel obstruction.

Relative contraindications:

» Multiply pre-operated patients.

» Morbid Obesity.

» Pregnancy - from the fifth months of gestation.

» Anesthetic risk, anesthetic complications.

» Malignant tumour.

Safe handling and preparations

Cautions:

» Please be ensured that the product and its accessories are used and handled only by persons who have the appropriate knowledge and experience.

» Read and follow the operating instructions.

» Use the device only as intended, see "Intended Use".

» Remove the shipping packaging and then manually or mechanically clean the new device according to current hospital regulations.

» Storage and transport temperature of the device is -10°C and +50°C. Store any new or unused product in a dry, clean and safe place.

» Inspect the product and its components every time before use for damages (i.e. loose, bent, cracked, broken, worn, damaged) and for defect.

» Replace any defective component with an original replacement, if available. If not available, please contact the manufacturer or the authorized distributor/service partner.

» Do not use the product if it is damaged or defective. Damaged, defective product must be stored separately.

» Take care to avoid possible damage to the components of related instruments during use: e.g. carefully insert the product into the trocars.

Risk of injury due to ignition or explosion of flammable gases! Sparks can occur when using an HF device.

» **Follow the safety guidelines of the HF device manufacturer's operating instructions.**

Risk of instrument damage and thermal injury to patient/users!

» **Adjust the HF device to an appropriate setting to ensure that the peak output voltage does match or not exceed the accessory voltage rating specified for the product.**

» Adjust the HF power output (and argon gas flow, if applicable) to the intervention to be performed. Consider clinical experience or reference values.

» Always set the lowest possible, but effective HF power output.

» Keep the product's contact surfaces clean during surgery. In the event of contamination, use a moistened cloth to remove tissue residues or body fluids from the product.

The device is equipped with the following HF connector for monopolar cables: Connector pin Ø4mm.

Please study our catalogues or consult the manufacturer/ authorized distributor for compatible cables.

The rated voltage of this device is 4,000 Vp.

The rated voltage of the instrument insulation must be higher or equal to the peak output voltage of the HF device used with it in the operating mode (see EN 60601-2-2).

To avoid HF burns:

» Always keep the active end of the product in the field of view when activating the HF power.

» Before activating the HF device, make sure that the active end of the product is not in contact with any electrically conductive accessories.

» Prior to each use, visually inspect the product for damages or surface changes to the insulation.

» Never place the product on or near the patient.

» Follow the instructions for use of the HF device.

Safe use

Risk of injury and/or malfunction!

» **Always perform a functional check before using this product.**

There is a risk of injury when using the product beyond the field of view!

» **Use the product only under visual control.**

» Make sure that the insert-moving mechanism works properly: Open and close the jaws / blades by opening and closing the handle.

Assembly

» Place the insert into the tube and push it in as deep as it could go (**A1**).

» Turn the instrument insert in the tube clockwise until it stops (**A2**).

» For instruments equipped with handles ELI-H3 (with ratchet): open completely the finger rest arm of the ratchet (**A3**).

» Push the metal button on the movable handpiece of the handle and then fully open the handle (**A4**).

» Hold the tube and push it together with the insert into the handle (**A5**). Please note that the jaws should be in completely open position. (Note: the tube with the insert can't be fully inserted into the handle, see next step).

» Fully close the handle arms (**A6**). This causes the handle to retract the tube and insert into its final position.

» Make sure that the instrument is mounted correctly. Check the operation of the device: the jaws are closed and opened unhindered when the handle is closed or opened.

Disassembly

» For instruments equipped with handles ELI-H3 (with ratchet): open completely the finger rest arm of the ratchet (**B1**).

» Push the metal button on the movable handpiece of the handle and then fully open the handle (**B2**). As a result, the tube and insert are released from the handle.

» Grasp the tube and pull the tube together with the insert out of the handle (**B3**).

» Turn the insert in the tube anticlockwise until it stops (**B4**) and then pull it out (**B5**).

CDS: cleaning - disinfection - sterilization process

General safety instructions

Follow all applicable national legal regulations, national and international standards and directives, local and clinical hygiene guidelines for the TFS procedure.

For patients with Creutzfeldt-Jakob Disease (CJD), suspected CJD or suspected CJD variants, follow the relevant national regulations for product CDS procedures.

You can only be sure about the successful CDS process of the product if the process has first been validated. The operator/sterile processing technician is responsible for this procedure.

General information

Cleaning of the device should be started within 30 minutes after surgical use.

Dried or stuck tissue residues and other impurities can make cleaning difficult or ineffective and can lead to corrosion.

Overly concentrated chemical can react chemically and/or fade and make the laser engraved markings on the stainless-steel surfaces unreadable.

Chemicals, salt, medicine residues on stainless steel surfaces may cause corrosion damage (pitting, stress corrosion) and should be rinsed thoroughly with demineralized water and then dried/wiped dry.

The product may be damaged if the cleaning / disinfecting agent and/or temperature are incorrectly selected!

» **Use approved chemicals for rigid endoscopic instruments.**

» **Observe the manufacturer's specifications regarding concentration, temperature and exposure time.**

The following are the manufacturer's validated cleaning/disinfection procedures. If the user is applying other chemicals or the cleaning machine is operating with different phases and/or parameters, it is the user's responsibility to validate the cleaning/disinfection procedure.

Mechanical cleaning/ disinfection

The device must be cleaned only when it is fully disassembled!

The washer-disinfector must comply with the requirements of standard ISO 15883-2.

Phase	Steps	Temp. [°C]	Time [min.]	Water quality	Reagent
1.	Washing	80	30	Deionized water	Neodisher Septo Clean
2.	Neutralize	30	10	I Deionized water	Neodisher Z
3.	Rinsing	30	10	Deionized water	-
4.	Drying	40	10	-	-

Checks and tests

» Allow the product to cool down to room temperature .

» After each cleaning, disinfection and drying cycle, check that the instrument is dry, clean, functional and undamaged (e.g. no broken insulation, corroded, loose, bent, broken, cracked or dented parts).

» Dry the product if it is wet or damp.

» Repeat cleaning and disinfection of the product if it remained contaminated.

» Assemble the product, see" Assembly ".

» Check that the product is working properly.

» Dispose of a damaged or malfunctioning product and return it to the manufacturer.

Packing

- Protect the delicate parts of the device (e.g., the jaws/inserts.
- Store the instrument inserts and handles in the open position.
- Place the product on a suitable instrument tray. Make sure all cutting edges are protected.
- Pack the tray according to the intended sterilization procedure.
- Ensure that the packaging provides adequate protection against product contamination during storage.

Sterilization

The device can only be sterilized only when disassembled and fully open!

Validated sterilization procedure: steam sterilization by fractional vacuum.

Phase	Method	Sterilization cycle		Drying
1.	Pre-vacuum	121 °C	20 min.	30 min.

The autoclave must comply with EN 285 and be validated according to EN ISO 17665.

When sterilizing multiple devices in the autoclave at the same time, make sure that the sterilizer does not exceed the maximum loading capacity specified its manufacturer.

If the user chooses a sterilization procedure other than described above, it is the user's responsibility to validate that sterilization procedure.

The product has been tested by the manufacturer and it has been certified to minimum 300 sterilization cycles. In clinical practice, the lifespan depends on individual use and the hospital's CDS technology.

Service

Risk of injury and / or malfunction!

» **Do not modify the product.**

For repair needs, please contact the manufacturer.

Any failure to repair, repair or modify the device by any unauthorized person will void the manufacturer's responsibility and will void the warranty immediately.

Disposal

Dispose of this product, its parts or packaging in accordance with the applicable national regulations.

Sterilize the product before disposal or recycling!

EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft.

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