Operating Instructions

Modular Hand Instruments for Laparoscopy

Made in Germany

Manufacturer: **Amnotec International Medical GmbH**
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Products:

- LAP-Dissecting scissors with HF connector
- LAP-Forceps with HF connector
  Items: 73-200-00 - 73-495-45 CR

By purchasing this instrument, you receive a quality product whose proper handling and use are presented below. In order to keep risks to patients and users as low as possible, we ask you to follow the instructions carefully. The application, disinfection, cleaning and sterilization of instruments must be carried out by trained specialists.

General Information

1. Inspect the instrument for cleanliness, functionality and for damage after each cleaning and disinfection and prior to each use. These may include warped, cracked, worn or fractured components, as well as damage to the insulation.
2. The LAP instruments can bear a traction force of up to 50N (approx. 5.0 kg). If these forces are exceeded, damage to the handles, electrodes, jaw parts, tie rods and joints may occur.
3. Do not use damaged or defective instruments. Replace damaged items immediately with original spare parts.
   To prevent damage to the electrodes, insert the instrument through the trocar.
   Visually check the instrument before each use for warped, broken, cracked, worn or fractured components. Exclude damaged instruments immediately.

Intended Purpose

Laparoscopy is an optical examination and diagnostic procedure in which the abdominal cavity and the organs contained therein (liver, gall bladder, spleen, uterus, etc.) are mirrored with an endoscope. During a laparoscopy, in addition to the diagnosis, surgical procedures and biopsies are also made possible whereby surgical micro-instruments are utilised. These instruments are inserted through a trocar into the abdominal cavity.
In accordance to procedures, micro-surgical (MIS instruments) laparoscopic instruments with HF connectors are utilised to manipulate, grip and cut tissues and organs. Amnotec GmbH´s separable laparoscopic instruments with HF connectors are suitable when using mono-polar HF current. If indicated, the instruments can be implemented for the specific coagulation of tissue and vessels.

Indications

- General abdominal surgery
- Surgical procedures of the bile ducts
- Abdominal and oesophageal surgical procedures
- Small intestinal surgical procedures
- Colonic surgical procedures
- Hernia repair procedures

Amnotec GmbH´s separable laparoscopic instruments with HF connectors are suitable when using mono-polar HF current.
In accordance to procedures, micro-surgical laparoscopic forceps with HF connectors (MIS instruments) can be used to grasp and dissect tissue, organs and blood vessels. When used in

conjunction with HF current, the instruments can be simultaneously used to dissect and coagulate tissue and vessels.

Contra-indications

- The products are solely designed for use with monopolar HF current. The use of products with bipolar HF current is contraindicative and can cause serious injury to the patient, users or third parties.
- The use of the products on patients with Pacemakers or other active implants should only be undertaken after the careful consideration of risks and after consultation with specialists.
- The products must not be used near flammable or explosive gases or other fire-sensitive media.
- The products are not suitable for use in single port laparoscopy. Due to the close proximity of other metallic instruments during these procedures, usage of monopolar HF current may lead to the unwanted deviation of the current (antenna coupling) and thus lead to serious complications (e.g. burns) away from the area of surgery.
- The products should only be used after making careful considerations regarding the suitability of laparoscopic surgical procedures using monopolar instruments and are contra-indicative for all other applications.
    - The products should solely be used "under direct vision". Coagulation should only take place if the instrument is in the field of view of the surgeon. This reduces the risk of unintentional contact with other metallic instruments.

Hazards

- Injury to nerves, blood vessels and organs
- Circulatory disorders (abdominal inflation due to the build-up of Carbon Dioxide, and in particular, patients with existing pulmonary disorders)
- Instrument breakage caused by the exertion of excessive force by the operator (extension of operating times and rarely, by the prolonged entrapment of fragments) or by stress corrosion cracking caused by faulty reprocessing
- Electrical burns
- Infections caused by incorrectly reprocessed instruments

Combination with other products / instruments

Components of Amnotec sets as well as Amnotec individual products are compatible with each other. Before using Amnotec single products/sets with products from other manufacturers, the user must ensure the application specific compatibility of the individual products.
The instruments can be connected to high-frequency generators manufactured by Olympus, Aesculap, KLS/Martin and to other similar devices. Please observe the notes in the operating instructions for the respective HF generator.

Accessories

HF cables should be selected in accordance to the HF generator (Olympus, Berchtold ...). There are no restrictions with the HF cables. The HF cables must be tuned to the HF generators.

Handling

1. The instruments must not be placed under excessive force whilst twisting or levering, as this may result in damage or breakage to the parts of the instrument.

2. When used as intended, the HF-device can cause sparks. There is a risk of injury from the ignition or explosion of combustible gases. The safety information contained within the operating instructions of the HF-device must be observed.
3. Regulate the output power of the HF-device in accordance to the procedure. Take into consideration clinical experience and references.
4. Maintain a clean contact surface area on the HF-device during the operation. Wipe away dried tissue residue or body fluids with a damp swab.
5. The insulation of the instrument is designed for a maximum rated alternating voltage of 2 kVp. Based on the operating instructions of the HF-device, check the ratio of the maximum rated alternating voltage to the HF modus and the configured dosage.
   To avoid unintentional HF burns, only use the instrument if the specified maximum rated voltage for the instrument is equal to or greater than the maximum set output voltage of the HF-device.
   The electrodes of the activated instrument must be in the field of vision of the user. Before activating the HF-device, ensure that electrodes of the instrument do not come into contact with any conductive accessories or any conductive liquids. In the case of endoscopic procedures, where contact with active instruments cannot be excluded, use insulated accessories. Prior to each use, visually inspect the insulation for damage and changes to the surface.
   Immediately replace damaged instruments and items with original spare parts.
   Switch off the “automatic power-on” modus on the HF-device.

Always observe the Operating Instructions of the HF-device.

Assembly

The instrument is to be **assembled** as follows:

1. a) ø3,5mm, ø5 mm and ø10 mm instrument inserts:
   Feed the instrument insert into the guide tube up to the thread and then tighten the screw. The two parts are thus joined together.
   b) ø3 mm attachments:
   These instrument attachments are not separable, i.e. the guide tube and the instrument insert are an inseparable, connected unit.
2. In the next step, either the separable ø3,5 mm, ø5 mm and ø10 mm instrument inserts and guide tube or the inseparable ø3 mm attachments are to be connected to the modular handle. Here, the jaws must be **completely closed** and the handle **completely open**, so that the receptacles for the instrument attachments are exposed to a maximum. Thereafter, mount the orb on the instrument attachment into the bore hole of the receiver on the handle.
3. The hinged instrument attachment will now be secured by closing the handle.
4. Tightly screw and attach the black union nut on the handle to the instrument attachment. Now the instrument is ready for use.

Disassembly

The instrument is to be **disassembled** as follows:

1. With the handles closed, unscrew the black union nut on the instrument attachment.
2. Remove the orb on the instrument attachment from the bore hole of the receiver on the handle.
3. Unscrew the instrument insert (ø3,5/5/10 mm) within the guide tube and remove.
4. Hereby, the instrument is completely dismantled.

Cleaning, sterilization and maintenance

Due to the design of the product and the materials used, it is not possible to set a defined limit to the maximum possible number of reprocessing cycles. The durability of medical devices is determined by their function and with consideration of their handling.
Before returning defective products for repair, ensure that they have been through the entire reprocessing procedure.

Preparation for processing

The instruments must be disassembled (and/or opened) before processing.

On-site preparation

Remove coarse dirt from the instruments directly after each use. Do not use a fixating agent or hot water (>40°C) as this can cause residues to fuse, which may influence the result of the reprocessing process.

Transportation

To avoid damaging the instruments and contamination of the environment, always store and transport instruments in sealed, closed containers.

Manual pre-cleaning

Prior to cleaning, the instruments must be disassembled. Under running water, use a soft brush to remove all visible contamination.
Clean cavities, bore holes and threads for at least 10 seconds with a pressure rinse water pistol (min. pressure 4 bar).
If the brushing / rinsing process does not lead to the required result, lay the instruments in cold water for a minimum period of 5 minutes.
Thereafter, place the instruments for 10 minutes in an ultrasonic bath and treat with a cleaning liquid (0.5%). Once completed, remove the instruments and rinse with a water pistol.

Mechanical cleaning

Cleaning / Sterilising equipment: G 7836 CD (Miele)

Cleaning program: **Oxivario**

Step	Time (min)	Stage of Process	Reagents	Temp. (°C)
1	3	Pre-cleaning	Mains water	Cold
2		Drain water		
3	3	Cleaning	Mains water Dosage: 0.5% Sekumatic FR (Ecolab) at 45°C	55
4		Drain water		
5	2	Cleaning	Mains water Dosage: 0.5% Sekumatic FR (Ecolab) at 45°C	55
6		Drain water		
7	1	Neutralisation	Deionized water	Cold

			Dosage: 0.1% Sekumatic FNZ (Ecolab)	
8		Drain water		
9	1	Rinse	Deionized water	Cold

Disinfection

Consider National requirements, in particular A0-values, when performing mechanical thermal disinfection processes.

Drying

Dry the outside of the instruments by utilising the drying cycle of the cleaner/steriliser.
In addition, when necessary, instruments can be dried manually using a lint free cloth. Instrument cavities can be dried using sterile compressed air.

Function tests / maintenance

Visual inspection of cleanliness, the assembly of instruments, maintenance and functional tests should all be carried out according to the operating instructions.
If necessary, repeat the reprocessing process until the instrument is optically clean.

Packaging

Standardised packaging for sterilised instruments according to EN ISO 11607 and EN 868

Sterilisation

Before the instrument components are prepared for sterilisation, the surface, and in particular, all the moving parts should be carefully lubricated. For this we recommend grease-free and temperature resistant silicone products. This enables moving parts and threads to remain viable and in addition, protects the entire surface of the instrument from mineral deposits that can later lead to functional impairments. The lubricants must be biocompatible and approved for use with medical devices. Please note that the instrument should be routinely lubricated after every cleaning (ultrasonic, etc.) and before each sterilisation.

Sterilisation of products with fractional pre-vacuum procedure (in accordance with EN ISO 17665) in consideration of the respective national requirements.

- 3 pre-vacuum phases with a pressure of at least 60 mBar
- Heating up to a sterilisation temperature of min. 132°C and max. 137°C
- Shortest exposure time: 5 min.
- Drying time: at least 10 min.

Storage

Store sterilised instruments in a dry, clean and dust-free environment at moderate temperatures, ranging from 5°C to 40°C.

Additional instructions

If the chemicals and machines described here are not available, and/or the treatment process as described does not perform, the user is obliged to validate the processes used accordingly.

Further information on the reprocessing of medical devices

- Internet: http://www.a-k-i.org
- Hygiene requirements involved in the reprocessing of flexible endoscopes and peripheral endoscopic instruments - recommendations by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), Internet: http://www.rki.de
- Hygiene requirements involved in the reprocessing of medical devices – recommendations by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) : "Hygiene Requirements for the Reprocessing of Medical Products"
- As the product is not re-sterilisable, please note: ISO 17664 Sterilisation of Medical Devices. Information that is to be provided by the manufacturer for the reprocessing of re-sterilisable medical devices

Warranty limitations

Amnotec GmbH guarantees to manufacture your products with the utmost care.

THIS IS THE ONLY VALID WARRANTY AND SUPERSEDES ALL OTHER DECLARATIONS OF WARRANTY.

It should be noted that due to the biological differences in individuals to be treated, no product is always completely effective under all conditions.

Amnotec GmbH has no influence on the applications of the product, the diagnosis of the patient and on the handling of the product outside of the company. Amnotec GmbH cannot guarantee effectiveness or even complication-free use of the product. Therefore, Amnotec GmbH assumes no liability for damages and costs. Amnotec GmbH will replace items which have a defect accepted by Amnotec GmbH.

Employees of Amnotec GmbH are not authorized to modify the above-mentioned conditions, to extend the liability or enter into additional product-related obligations.

Products are subject to change.

Explanation of Symbols:

	Reference number
	Lot number
	Refer to operating instructions
	Attention – refer to accompanying documents
	Caution – Non-sterile product
	CE-Mark and Registration number of the designated Body mdc medical devices certification GmbH