IFU Laparoscopy grasping forceps and scissors with HF-connection, monopolar

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CE 0123

Products: Laparoscopy grasping forceps and scissors with HF-connection, monopolar with the number range
92.010.21A to 92.200.16.
The following items are excluded:

- All articles with the length >450mm.

It is essential to read this manual before using Dimeda instruments and accessories.

⚠ General Information

- Please read these instructions for use carefully before using the surgical instruments. Improper and/or incorrect handling can have far-reaching consequences for the patient and/or user or cause premature wear.
- The user is ultimately responsible for checking the function and sterility. Surgical instruments and accessories, which are damaged and/or not fully functional, must not be used. These must be replaced immediately with original spare parts.
- With the purchase of this instrument, you receive a high-quality product whose proper handling and use are described below.
- In order to minimize hazards for patients and users, please follow the instructions for use carefully. Trained specialists may only carry out the use, disinfection, cleaning and sterilization of the instruments.
- Persons who have the appropriate knowledge of their use and application may only use the surgical instruments and accessories. Dimeda accepts no liability for direct damage and consequential damage in the event of incorrect handling, improper use and failure to observe the intended use as well as improper preparation and maintenance.
- The LAP instruments can be loaded with tensile forces of up to 50 N (approx. 5.0 kg). If these forces are exceeded, damage can occur to the handles, working ends/mouth parts, tie rods and joints.
- To avoid damage to the working end, insert the instrument carefully through the trocar sleeve.

⚠ Before Use

Check instrument after each cleaning, disinfection and before each use for: cleanliness, function and damage, e.g. insulation, surface such as scratches, cracks, nicks, notches etc. as well as bent parts. If these defects are present, the instruments must not be used. The product then requires repair or disposal in accordance with clinical/practical practice. Do not use damaged products.

⚠ Indication

- General abdominal surgery
- Interventions on the bile ducts
- Esophageal and gastric interventions
- Interventions on the small intestine
- Colon interventions
- Hernia closures

The different working lengths of the products are to be applied as follows:

- Ø3mm, Ø3.5mm, Ø5mm and Ø10mm instruments with a working length of 220mm and 250mm are normally used in pediatrics.
- Ø3mm, Ø3.5mm, Ø5mm and Ø10mm instruments with a working length of 330mm are normally used in normal weight patients.
- Ø3mm, Ø3.5mm, Ø5mm and Ø10mm instruments with a working length of 450mm are usually used in patients with obesity.

⚠ Contraindication

- The products are designed exclusively for use with monopolar HF current. Use of the products with bipolar HF current is contraindicated and may result in serious injury to the patient, user or third parties.
- The products must not be used approximately flammable or explosive gases or other fire-sensitive media.
- The products are not suitable for use in single port laparoscopy. The close proximity to other metallic instruments during these procedures can lead to unintentional current leakage (antenna coupling) when using monopolar RF current, resulting in serious complications such as burns Away from the surgical field.
- The products should avoid any contact with titanium alloys, as material changes may occur due to the RF current.
- The products should only be used under careful consideration regarding the suitability of laparoscopic procedures using monopolar instruments and are contraindicated for all other uses.
- The products should only be used "under sight". Coagulation should only be performed when the instrument is in the surgeon's field of view. This reduces the risk of unintentional contact with other metallic instruments.

⚠ Risks and Complications

- Injury to nerves, vessels and organs.
- Circulatory disorders (especially in patients with diseases of the cardiovascular system of the lungs caused by the inflation of the abdominal cavity with carbon dioxide).
- Instrument fractures due to excessive force exerted by the surgeon (prolongation of operating time, rarely: prolonged confinement of fragments) or due to stress corrosion caused by incorrect reprocessing.
- Combustion by electricity.
- Infections caused by incorrectly reprocessed instruments
- Capacitive coupling (with two current-carrying conductors, consequential error: can lead to temperature development).

RF current can damage pacemakers. Consult a cardiologist before the procedure.

⚠ Intended Use

The dismountable laparoscopic instruments with HF connection from Dimeda are intended for use with monopolar HF current.
Depending on the work application, the microsurgical laparoscopy grasping forceps (MIS instruments) with HF connection are used for grasping, dissecting tissue, organs and vessels. Laparoscopic scissors with HF connection are used for cutting tissue, organs and vessels. When using HF current, the instruments are used to dissect and simultaneously coagulate tissue and vessels.

⚠ Combination with other Products / Instruments

Components of Dimeda sets and Dimeda individual products are compatible with each other. The use of Dimeda individual products/sets with third-party products is not permitted. Dimeda instruments can be connected to the following HF-generators with the appropriate cables.

Manufacturer	Generator	Cable
Aesculap	GN640	GN202
Olympus	ESG-400	A0392
KLS Martin	ME 102	80-332-03-04
Berchtold	Elektrotom 80/80 B	90.280.31

Handling

1. The instruments must not be overstressed by twisting or levering, as this may result in damage or breakage of instrument parts.
2. Sparks may be generated during the intended use of the HF device. Risk of injury due to ignition or explosion of flammable gases. It is essential to observe the safety instructions in the operating manual of the HF device.
3. Match the RF output power to the procedure. Consider clinical experience or references.
4. Keep the contact surface of the instrument clean during surgery. Wipe off dried tissue residues or body fluids with a moist swab.
5. The instrument insulation is designed for a maximum recurring rated voltage of 2 kVp. Check in the operating instructions of the HF device: maximum recurring output voltage depending on HF modes and set dose.
   To avoid unintentional HF burns: Only use the instrument if the rated voltage specified for the instrument is equal to or greater than the maximum set output voltage of the HF device.
   Keep the working end of the activated instrument within the user's field of view. Before switching on the HF device, ensure that the working end of the instrument is not in contact with any conductive accessories or liquids. If contact with active instruments cannot be ruled out during endoscopic procedures, use insulated accessories. Before each use, visually inspect the insulation for damage and surface changes. Immediately replace damaged instrument and individual part with original spare parts. Switch off the automatic switch-on mode of the HF device.

Always follow the operating instructions for the HF device.

⚠ Assembly

The instrument is assembled as follows:

1. a) ø 3.5mm, ø 5mm and ø 10mm instrument inserts:
   Insert the instrument insert into the guide tube up to the thread and then screw the thread into the guide tube as far as it will go. The two parts are then connected to each other.
   b) Ø 3mm instrument attachments:
   These instrument attachments cannot be disassembled, i.e. guide tube and instrument insert are an inseparable connected unit.
2. In the next step, the instrument attachment (ø 5/10mm), consisting of a guide tube with screwed-in instrument insert or the non-dismountable ø3mm instrument attachment, is connected to the modular handle. The jaw must be completely closed and the handle completely open so that the holder for the instrument attachments protrudes from the handle as far as possible. The ball on the instrument attachment is now hooked into the hole of the holder on the handle.
3. The inserted instrument attachment is now fixed by closing the handle.
4. Now the instrument attachment is firmly connected to the handle by tightening the black cap nut. The instrument is now ready for use.

Disassembly

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

1. The black cap nut on the instrument attachment is unscrewed from the handle when it is closed.
2. The ball of the instrument attachment is removed from the bore of the holder of the handle.
3. The instrument insert (ø 3.5/5/10mm) is unscrewed from the guide tube and pulled out of the guide tube.
4. The instrument is completely disassembled.

⚠ Reprocessing Information (according to SMP-Project no. 14119)

Due to the product design and the materials used, 50 reprocessing cycles can be performed for the inserts and "inserts firmly mounted on the shaft" and 100 reprocessing cycles for the handles. Due to wear and damage from use and reprocessing, instruments must be inspected prior to use and, if necessary, discarded before reaching the specified reprocessing cycles. Defective products must have undergone the entire reprocessing process before being returned for repair.

Manual Reprocessing

A manual reprocessing procedure is unsuitable. Manual cleaning/disinfection cannot guarantee a consistent and reproducible cleaning result and therefore mechanical reprocessing must be used.

⚠ Reprocessing Instructions for Automatic Reprocessing according to SMP Validation Project no. 11515-1 / 11515-2

General

The values / parameters of the processes described here were used in the validation carried out and are to be adopted accordingly depending on the existing conditions on site.

Remove coarse dirt from the instruments immediately after use. Do not use fixing agents or hot water (>40°C), as this leads to fixing of residues and can influence cleaning success.

Preparation of Reprocessing
The instruments may have to be disassembled or opened for reprocessing.

Transport
Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination towards the environment.

⚠Manual Pre-Cleaning

- Disassemble the instrument.
- Pressure flush the shaft with a water gun for 10 seconds (static pressure 3.8 bar). To flush the shaft, the 30-5100-905 flushing adapter is used.
- Soak the instruments in cold water for 5 min.
- Brush the instruments using a suitable brush until all visible residues are removed.
- Pressure-flush all openings and hard-to-reach surfaces, bores and threads with a water gun for 5 seconds each (static pressure 3.8 bar). Pressure-flush the cavities with a water gun for 10 seconds. The flushing adapter 30-5100-905 is used to flush the shaft.
- Place the instruments in an ultrasonic bath for 10 min and sonicate them in the cleaning solution (0.5% neodisher MediClean forte, 40°C).
- Pressure flush the cavities with a water gun for 10 seconds (static pressure 3.8 bar). The flushing adapter 30-5100-905 is used to flush the shaft.

Automatic Cleaning
Now place the laparoscopy instruments in an instrument sieve. Then start the following process:
Washer-Disinfector: G 7836 CD (Miele) SN: 9230557, Cleaning program: Vario TD

Step	Time (min)	Process step	Reagents	Temp. (C°)
1	2	Pre-cleaning	Tap water	10 - 25
2		Drain water		
3	5	Clean	Tap water Dosage: 0,5% Neodisher Mediclean (Dr. Weigert, Hamburg)	55
4		Drain water		
5	3	Flush	Deionized water	10 - 25
6		Drain water		
7	2	Flush	Deionized water	10 - 25
8		Drain water		

Disinfection
Carry out the mechanical thermal disinfection in accordance with the national regulations and the A0 value = 3000.

Drying
Drying of the outside of the instruments by the drying cycle of the washer/disinfector. If necessary, additional manual drying can be achieved using a lint-free cloth. Drying instrument cavities with sterile compressed air.

Functional testing, Maintenance
Visual inspection for cleanliness; reassembly of the instruments, care and function test according to the operating instructions. If necessary, repeat the reprocessing process until the instrument is visually clean.

Packaging
Standard-compliant packaging of instruments for sterilization according to EN ISO 11607 and EN 868

⚠Sterilization according to SMP validation Project no. 11615

Before the instrument components are prepared for sterilization, the surface and especially all moving parts should be carefully lubricated. We recommend an instrument oil here, which is permeable to water vapor so as not to negatively influence the result of the sterilization. This helps to ensure that the moving parts and threads remain operable and protects the entire instrument surface from mineral deposits that can later lead to functional impairment. The products used for lubrication must be biocompatible and approved for medical devices. Please note that this lubrication of the instrument should be performed routinely after each cleaning (ultrasound, etc.) and before each sterilization. Sterilization of the products with fractionated pre-vacuum process (EN ISO 17665) taking into account the respective national requirements.

- 3 pre-vacuum phases with at least 60 millibar pressure
- Heating up to a sterilization temperature of 132°C
- Holding time: 3 to 5 min.
- Drying time: 10 min.

If contamination with prions (CJD) is suspected, reprocess and dispose of the instrument.

⚠Storing
Store the sterilized instruments in a dry, clean and dust-free environment at approx. 25°C without large temperature fluctuations.

Additional Instructions
If the chemicals and machines described here are not available, and if the reprocessing process cannot be carried out as described, it is the responsibility of the user to validate his process accordingly. It is the user's duty to ensure that the reprocessing process, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require compliance with validated processes.

Further Information on the Reprocessing of Medical Devices

- Internet: http://www.a-k-i.org
- Hygiene requirements for the reprocessing of flexible endoscopes and additional endoscopic instruments Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI), Internet: http://www.rki.de
- Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Requirements for hygiene in the reprocessing of medical devices"
- For information, as the product is resterilizable: DIN EN ISO 17664 Sterilization of medical devices. Information to be provided by the manufacturer for the preparation of resterilizable medical devices

Warranty Limitation
Dimeda guarantees to manufacture your products with the greatest possible care.

THIS IS THE ONLY VALID WARRANTY AND IT REPLACES ALL OTHER WARRANTY STATEMENTS GIVEN.

It should be noted that due to the biological differences of the persons to be treated, no product is always absolutely effective under all conditions. Dimeda has no influence on the application of the product, on the diagnosis of the patients and on the handling of the product outside the company. Dimeda can guarantee neither a good effect nor a complication-free application of the product. Therefore, Dimeda does not assume any liability for damages and costs. Dimeda will replace products that show a defect that has been accepted by Dimeda.

Employees of Dimeda are not entitled to change the above-mentioned conditions, to extend liability or to enter into additional product-related obligations.

Products are subject to changes.

Explanation of Symbols
According to DIN EN ISO 15223-1, the symbols shown on the medical device label or instructions for use have the following meaning:

REF	Item Number
LOT	Lot Number
MD	Medical Device
	Follow the Operating Instructions
	Follow the Instructions for Use
	Attention, observe accompanying documents
NON STERILE	Product non-sterile
CE 0123	CE-Symbol with identification number of the notified body TÜV Süd GmbH
	Pacemaker Icon
	Manufacturer
	Date of Manufacture
	Do not use if packaging is damaged
	Store dry
Rx only	To be used by qualified personnel only
	Type BF: Galvanically isolated applied part (F stands for floating) that meets the requirements for leakage currents for type B.
	Type CF: Galvanically insulated application part (F stands for floating) that meets even higher requirements for leakage currents than type B. Also suitable for direct application to the heart.

⚠Reporting obligations
All serious incidents occurring in connection with the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established, shall be reported immediately.