Operating Instructions

Modular Hand Instruments for Laparoscopy

Manufacturer: **DIMEDA Instrumente GmbH**
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Made in Germany

Products:

- LAP-Dissecting scissors with HF connector
- LAP-Forceps with HF connector

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.

These instruction is for use apply to all items with the number range 92.010.21A - 92.200.16. The following articles are excluded:

- All articles with the length >450mm.

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. DIMEDA Instrumente 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

DIMEDA Instrumente GmbH's separable laparoscopic instruments with HF connectors are suitable for using monopolar HF current.

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In accordance to procedures, micro-surgical laparoscopic forceps with HF connectors (MIC 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.

The different working lengths of the products are as follows:

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

Contra-indications

- The products are solely designed for use with mono-polar HF current. The use of products with bipolar HF current is contra-indicative and can cause serious injury to the patient, users or third parties.
- The products must not be used in the vicinity of 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 interventions can lead to the unwanted dissipation of the current (antenna coupling) and thus to serious complications such as burns away from the operating field when using monopolar HF current.
- The products should only be made with careful consideration of the suitability of laparoscopic procedures using monopolar instruments and are contraindicated 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
- Capacitive coupling (with 2 conductors flooded with current, consequential error: can lead to temperature development)


HF current can damage cardiac pacemakers. Before the procedure, Consult cardiologists.

Combination with other products / instruments


Components of DIMEDA sets and DIMEDA individual products are compatible with each other. The use of DIMEDA single products / sets with Third-party products are not permitted.

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The Dimeda instruments can be connected to the following HF generators with the appropriate cables:

Manufacturer	Generator	Electric wire
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 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

<u>The instrument is to be **assembled** as follows:</u>

1. a) ø5 mm und 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 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 product design and the materials used, 50 reprocessing cycles can be carried out for the inserts and "inserts firmly attached to the shaft" and 100 reprocessing cycles for the handles.
Defective products must have gone through the entire reprocessing process before being returned for repair.

Preparation for processing

The instruments must be disassembled or opened for reprocessing.

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

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

Manual pre-cleaning

1. Disassemble the instruments
2. Flush the stem with a water gun for 10 seconds (static pressure 3.8 bar). The flush adapter 30-5100-905 is used to flush the shaft.
3. The instruments for 5 min. soak in cold water
4. Brush the instruments with a soft brush until all visible residue is removed.
5. Flush all openings and hard-to-reach areas, bores and threads with a water gun for 5 seconds each (static pressure 3.8 bar). Flush the cavities with a water gun for 10 seconds. The flush adapter 30-5100-905 is used to flush the shaft.
6. The instruments 10 min. Place in an ultrasonic bath for a long time and sonicate in the cleaning solution (0.5% neodisher MediClean forte, 40 ° C).
7. Flush the cavities with a water gun for 10 seconds (static pressure 3.8 bar). The flush adapter 30-5100-905 is used to flush the shaft.

Manual cleaning

1. Disassemble the instruments
2. Flush the stem with a water gun for 15 seconds (static pressure 3.8 bar). The flush adapter 30-5100-905 is used to flush the shaft.
3. The instruments for 5 min. place in the cleaning solution (0.5% neodisher MediClean forte, 40 ° C).
4. Brush the instruments with a soft brush until all visible residue is removed.
5. Flush all openings and hard-to-reach areas, bores and threads with a water gun for 5 seconds each (static pressure 3.8 bar). Flush the shaft with a water gun for 15 seconds. The flush adapter 30-5100-905 is used to flush the shaft.

6. The instruments 9 min. Place in an ultrasonic bath for a long time and sonicate in the cleaning solution (0.5% neodisher MediClean forte, 40 ° C).
7. Flush the stem with a water gun for 60 seconds (static pressure 3.8 bar). The flush adapter 30-5100-905 is used to flush the shaft. And then rinse the outer surfaces with cold water for 60 seconds while moving the moving parts.

Mechanical cleaning

Cleaning / Sterilising equipment: G 7836 CD (Miele)

Cleaning program: **Oxivario**

Step	Time (min)	Stage of Process	Reagents	Temp. (°C)
1	2	Pre-cleaning	Mains water	Cold
2		Drain water		
3	5	Cleaning	Mains water Dosierung: 0.5% Neodisher MediClean Forte (Dr. Weigert, Hamburg)	55
4		Drain water		
5	3	Neutralisation	Deionized water	10-25
6		Drain water		
7	2	Rinse	Deionized water	10-25
8		Drain water		

Disinfection

Carry out mechanical thermal disinfection taking into account the national regulations and the A0 value = 3000.

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 for cleanliness; Assemble the instruments, care and function test according to the operating instructions.
If necessary, repeat the reprocessing process until the instrument is optically clean.

Packaging

The instruments are double in sterilization bags packed (Wipak STERIKING flat rolls type R43 / Type R44) according to EN ISO 11607-1.

Sterilisation

Sterilizer: Selectomat HP 666-1HR

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 helps to keep the moving parts and threads accessible and also protects the entire instrument surface from mineral deposits, which can later lead to functional impairments. The lubrication products must be biocompatible and approved for medical devices. Please note that this instrument lubrication should be carried out routinely after each cleaning (ultrasound etc.) and before each sterilization.

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

If you suspect contamination with prions (CJD), prepare and dispose of the instrument.

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 the preparation process cannot be carried out as described, it is the responsibility of the user to validate their process accordingly.

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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

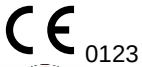
DIMEDA Instrumente GmbH guarantees to manufacture your products with the utmost care.
THIS IS THE ONLY VALID WARRANTY AND SUPERSEDES ALL OTHER DECLARATIONS OF WARRANTY.
It should be noted that due to the biological differences in individuals to be treated, no product is always completely effective under all conditions.

DIMEDA Instrumente 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. DIMEDA Instrumente GmbH cannot guarantee effectiveness or even complication-free use of the product. Therefore, DIMEDA Instrumente GmbH assumes no liability for damages and costs. DIMEDA Instrumente GmbH will replace products that have a defect that has been accepted by DIMEDA Instrumente GmbH.

Employees of DIMEDA Instrumente 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
	Follow the instructions
	Attention – refer to accompanying documents
	Caution – Non-sterile product
	CE Zeichen mit Kennnummer der benannten Stelle TÜV Süd Product Service GmbH
	Pacemaker symbol
	Is a medical device
	Manufacturer
	Date of Manufacture
	Do not use if the packaging is damaged
	Store dry
	To be used only by specialist personnel
	Type F: galvanically insulated application 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), which fulfills even higher requirements for leakage currents than type B. Also suitable for direct use on the heart.