Laparoscopic Instruments – Operating Instructions

PRODUCT DESCRIPTION / INTENDED USE
Instruments for laparoscopic surgery are intended for cutting, preparing, resecting, gripping and sewing of body tissue. Read the following instructions in the sequence given in order to achieve optimum results in maintenance, cleaning and sterilization. Prior to using the instruments observe all Warnings, Cautions and Notes.

WARNING
Immediately after unpacking inspect the instruments for transport damage and check their proper function. Any damage must be reported without delay. The product is shipped in NON-STERELE condition. Therefore, instruments must be cleaned, disinfected and sterilized before each use. The jaw parts may be sharp or pointed – be careful when handling.

When using laparoscopic instruments together with an HF generator always test the HF output power on the basis of the user's experience, clinical references and/or relevant training and education.

When using HF equipment always follow the HF unit manufacturer's instructions!
UNDER NO CIRCUMSTANCES EXCEED 5,000 V (PEAK TO PEAK). The instruments must not be used under the following conditions:
– if the electrode/instrument insert is loose or damaged, the insulation of the shaft shows cracks or the connector is loose or wrongly connected. The use of instruments with damaged insulation, defective electrodes/ instrument inserts or defective connectors may cause uncontrolled electro-surgical burns.
– if scratches, surface defects or fissures are visible on the instrument housing. The use of a defective instrument or an instrument that becomes defective during surgery may result in loose parts that could drop into the field of operation.
– if the connecting cable does not completely cover the electrical connector. This may result in an uncontrolled current flow.
– if large quantities of residue build up at the tool portion or if explosive gas concentrations are present in the field of operation.
Always check the compatibility of the instruments and ensure an uninterrupted equipment ground connection before using the system.

CAUTION
In order to prevent the instrument from damage it should be disassembled and sterilized in the opened position. Quick sterilization methods MUST NOT be used as the standard sterilization procedure since this may cause damage to the instrument. Do not use excessive force when handling the instrument since this may cause the jaw parts or the instrument to break. Applying undo force to turn the instrument while the tool portion is under load may damage the instrument insert. Excessive force on the handles while the instrument insert is holding on to an object may damage the insert. The instrument functionality should be checked before the surgeon uses the instrument. Should there be any indication of a malfunction the instrument must not be used and should be returned immediately to GIMMI® for checking and repair.

Repairs of GIMMI® products by non-authorized personnel can lead to malfunctions of the instrument and/or breakage of the jaw parts.

WARRANTY
GIMMI® GmbH guarantees that all products are free from defects in material and workmanship at the time of purchase. All components carry a one year warranty from the date of purchase. This warranty, that applies to all GIMMI® products, is limited to free repair or product replacement upon return of the defective product to GIMMI®GmbH. GIMMI® assumes no responsibility for the cost and risk of shipping. Instruments must be CLEANED, DISINFECTED and STERILIZED before returning them for maintenance or warranty work. This warranty does not apply to products that have been subjected to normal wear, unintended use, misuse, negligence, faulty installation or wrong application or which have been modified, readjusted, repaired or manipulated by unauthorized maintenance personnel.

Assembling the GIMMI® ALPHATRIPART System with PEEK handle without lock

Slide the instrument insert (12) into the shaft (11) and screw it in finger-tight.

With the instrument handle fully opened insert the pre-assembled shaft (11 + 12) into the rotating knob (8) all the way to the stop. Only hold the non-moving handle arm (4) in position. The moving arm (5) closes when the instrument insert hits the stop.

Fully tighten the fixation nut (9) by hand while holding the rotating knob (8) in position.
Confirm the proper instrument function.

!!! When using HF equipment always follow the HF unit manufacturer's instructions regarding output power and equipment connections.
For suitable HF connecting cables see Surgical Catalog # 140.

Disassembling the GIMMI® ALPHATRIPART System with PEEK handle without lock

Screw the instrument insert (12) out of the shaft (11) (which may require some force). The thread is located at the distal end.

Open the fixation nut (9) while holding the rotating knob (8) in position and pull out the shaft with the instrument insert (11 + 12). Do not hinder the movement of the moving arm handle arm (5).

Assembling the GIMMI® ALPHATRIPART System with PEEK multifunctional handle

Slide the instrument insert (12) into the shaft (11) and screw it in finger-tight.

Press down the lever (1) to deactivate the lock (3). Fully open the instrument handle. With the instrument handle fully open insert the pre-assembled shaft (11 + 12) into the rotating knob (8) all the way to the stop. Only hold the non-moving handle arm (4) in position. The moving arm (5) closes when the instrument insert hits the stop.

Fully tighten the fixation knob (9) by hand while holding the rotating knob (8) in position. Confirm the proper instrument function.

!!! When using HF equipment always follow the HF unit manufacturer's instructions regarding output power and equipment connections.
For suitable HF connecting cables see Surgical Catalog # 140.

Working principle of the PEEK multifunctional handle

For activating the lock (3) press down the lock actuator (2) and the lever (1) will move automatically outward.
In order to release the lock press down the lock actuator (2).

For deactivating the lock (3) permanently simply press the lever (1) in the direction indicated by the arrow until it engages.

NOTE:
For sterilization always activate the lock

Disassembling the GIMMI® ALPHATRIPART System with PEEK multifunctional handle
Press down the lever (1) to deactivate the lock (3). Open the fixation nut (9) while holding the rotating knob (8) in position and pull out the shaft with instrument insert (11+ 12). Do not hinder the movement of the moving handle arm (5).

Screw the instruments insert (12) out of the shaft (11) (which may require some force). The thread is located at the distal end.

Laparoscopic Instruments
MAINTENANCE INSTRUCTIONS/DISINFECTION/STERILIZATION

WARNING
1. Wear suitable protective clothing (gloves, eye protection, etc.) when using, cleaning or sterilizing this product.
2. Hand-held laparoscopic instruments from GIMMI® are shipped in NON-STERILE-condition. Therefore, before the first and any subsequent use clean, disinfect and sterilize the instrument according to the instructions below.
3. During use the instrument must not contact other metallic parts. Any contact with metal parts may damage the instrument. The use of defective instruments can result in loose parts that could drop into the field of operation.
4. Before returning an instrument for maintenance or warranty work it must be cleaned, disinfected and sterilized.

CAUTION
1. The quality of the water used for cleaning and steam sterilization influences the performance and the service life of the instruments. Only use fully desalinated water.
2. Do not use brushes or cloth containing metallic or abrasive substances for cleaning and disinfection of instruments since this may cause permanent scratches or damages.
3. Always observe the time of exposure to solvents specified by the solvent manufacturer in order to prevent corrosion and other damages.
4. The instruments must not be immersed in saline as this may cause corrosion.
5. Do not use strong acidic or basic solutions as these can cause damage to the instrument.
6. When cleaning instruments in an ultrasound unit do not put them on the chamber bottom since this may cause damage or incomplete cleaning. Always follow the instructions of the equipment manufacturer.
7. When disinfecting or sterilizing instruments with multifunctional handle always activate the lock.

NOTE
1. The service life of the product depends primarily on its wear, the damages due to rough handling and the adherence to the intended use.
2. Damages caused by incorrect handling are not covered by warranty.

CLEANING AND DISINFECTION

WARNING Wear suitable protective clothing: gloves, eye protection, and the like.
We recommend cleaning/disinfection by machines with subsequent steam sterilization at 134 °C (272 °F). Always follow the instructions of the equipment manufacturer.

1. Immediately after each use immerse the instrument in a mild enzymatic cleaning solution in order to remove any blood, protein and phlegm. Observe the concentrations, temperatures and duration specified by the supplier of the enzyme. Ensure that all parts and components are open so that the enzymatic cleaning solution produces its optimum efficiency.

CAUTION Do not use strong acidic or basic solutions as these can cause damage to the instrument:
2. Rinse the instruments thoroughly under warm running water that is fully desalinated. If an instrument is provided with a rinsing device this should be flushed thoroughly.
3. If the use of an ultrasound cleaning unit is part of the cleaning procedure:
   • Put the instrument in an instrument basket with a stainless steel grid bottom and place the basket in the ultrasound cleaning unit.
   • Observe the recommendations of the manufacturer relating to cleaning duration, cleaning solutions, water treatment, bath exchange interval and basket position.
4. Place the instruments in a mixture of enzymatic solution and a mild cleanser. This prevents premature wear or instrument malfunction by “lubricating” the internal components. Adhere to the concentrations, temperatures and exposure times recommended by the solution manufacturer.
5. Use a clean and soft hand brush to clean all surfaces of the instrument immersed in the cleaning solution in both the open and closed position. Completely clean all channels or lumina of the instrument using a soft brush.
6. Thoroughly rinse all parts and lumina under warm running water that is fully desalinated.
7. Immediately after rinsing use a lint-free cloth or compressed air to completely dry all parts.
8. Ensure that the instruments are clean and dry. Should tissue or fluid accumulations persist, the cleaning and disinfecting process described above must be repeated.

WARNING All tissue and liquid residues must be removed before sterilization.
Lubricate all joints with silicone oil (e.g. J.8860.06). In case of multifunctional handles activate the lock before disinfection/-sterilization.
TESTING AND MAINTENANCE
1. Following each cleaning and disinfection please test and confirm the proper function and safety of each instrument. If there is any reason to suspect a problem take the respective instrument immediately out of order for later repair.
2. Check all tool portions, indexing elements and cutting edges for damage. All tool portions must be correctly aligned and must fully open and close easily.
3. In case of electro-surgical instruments check the electrical insulation of the insert and/or the handle for burns and mechanical damage. Only use completely dry instruments.

STERILIZATION
1. Clean the instruments as described in section CLEANING AND DISINFECTION.
2. Disassemble the instruments if not specified differently. All joints must be lubricated with oil (e.g. J.8860.06). The Alpha TriPart instrument can be sterilized when assembled after proper cleaning. It is a critical part of this validation that the luer lock cleaning port cap on the shaft is left open for proper steam penetration. This sterilization method has been validated by Medical Device Testing; project #09m087.
3. Where necessary, place the instruments in sterilization containers suitable for the purpose.
4. Store the instruments in a cool and dry place.

DATA FOR STEAM STERILIZATION

Pre-vacuum cycle /validated sterilization process (3 times fractionated pre-vacuum)
Packaged
Temperature: 134°C (270°F - 272°F)
Min. sterilization time: 4 minutes
Min. drying time: 10 minutes

Other possible processes (Hospital should have validation of their sterilization process)
Gravitation
Packaged
Temperature: 134°C (272°F)
Min. sterilization time: 18 minutes
Min. drying time: 8 minutes

Packaged
Temperature: 121°C - 123°C (250°F - 254°F)
Min. sterilization time: 50 minutes
Min. drying time: 8 minutes

Not packaged (flash)
Temperature: 132°C - 134°C (270°F - 272°F)
Min. sterilization time: 25 minutes

WARNING Flash sterilization should not be used if sufficient time is available for steam sterilization. Repeated flash sterilization may have an aggressive effect on the instrument insulation and may affect the safety and performance of the instrument.

DATA FOR ETHYLENE OXIDE (EO) STERILIZATION
EO/OXYFUME 2002
Package the instrument and place it on an instrument tray or in a suitable sterilization container.
Preparation parameters
Temperature: 55°C ± 2°C
Relative humidity: 70% ± 5%
Preparation time: 1 hour

Sterilization parameters
Ethylene oxide carrier: Oxyfume 2002
Temperature: 55°C ± 2°C
Relative humidity: 70% ± 5%
Pressure (psig start): 1,75 bar (25,4 psig)
EO concentration: 600 ± 25 mg/l
Sterilization time: 4 hours
Aeration time: 12 hours at 55°C (131°F)

100% EO
Package the instrument and place it on an instrument tray or in a suitable sterilization container.
Preparation parameters
Temperature: 43°C ± 2°C
Relative humidity: 65% + 10% / -20%
Preparation time: 1 hour

Sterilization parameters
Temperature: 55°C ± 2°C
Relative humidity: 70% ± 5%
EO concentration: 600 ± 25 mg/l
Sterilization time: 4 hours
Aeration time: 12 hours at 55°C (131°F)