

## INSTRUCTIONS FOR USE

### Important instructions for use!

Please read this information before using the instrument!

By purchasing this instrument you have decided for a German high quality product. To ensure the function and safety of the instrument at long sight please observe the following points:

### First use of new instruments

All instruments of Peter Lazic GmbH are delivered in non-sterile condition and must be cleaned and sterilized before using. Therefore, please pay attention to the following instructions (see chapter "Preparation (cleaning, disinfection and sterilization)"). Exempted from that are all instruments marked with the comment "sterile".

### Safety control

Before each use, it is important to inspect (optical control) the instrument. Make sure that there are no cracks, breakings or mechanical malfunctions. Pay attention to defaults on critical points such as tips, cuttings, lockings and on all movable parts.

### Usage/Application

The microsurgical instruments are intended for the microsurgical.

Interventions in the microsurgical target area must be performed in an extremely narrow space, sparing neighboring sensitive structures. Various precision instruments are used for displaying, removing, cutting through and reuniting tissue structures. This micro-equipment e.g. comprises forceps, tweezers, scissors, dissectors etc., which assume these functions and at the same time transfer the tactile properties.

The L-Line Memory Micro Instruments can furthermore be used for endoscopically-supporting surgeries as well as for endonasal access.

### Benefits

- Particularly gracile, delicate jaw parts allow precise surgery
- Better balance – good hand rest between thumb and index finger
- Bayonet-shaped axial shaft (L-Line MEMORY) for improved sight and handling

### Contraindications

- The microsurgical instruments may only be used for their intended purpose. They are contraindicated for all other applications.
- The microsurgical instruments should only be used in combination with optical magnification aids (surgical microscope / surgical loops).
- Allergy to material components (1.4021, 3.7165, 1.4034, 1.4301, 1.4310, 1.4305, PTFE, 1.4021, NiTi wire, ALMGSI1, NiTi tube)

### Handling

Treat the surgical instruments always with the necessary care. Take measures for protection against damages in transporting, cleaning, maintenance, sterilization and storage.

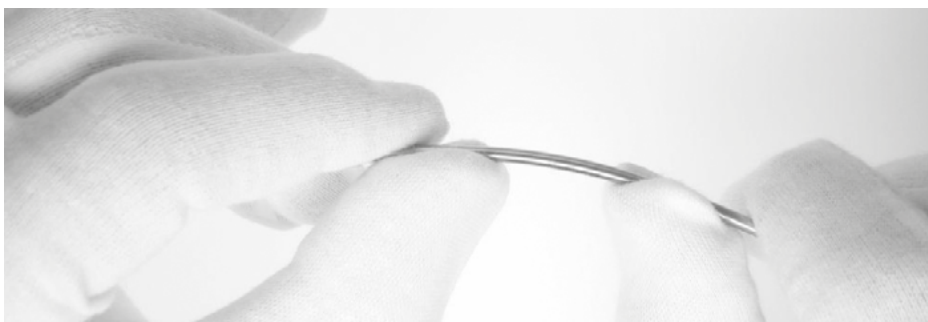
Avoid the contact of the instruments with abrasive substances (see chapter "Resilience of the material"); this can result in corrosion and damage of function right up to complete uselessness. This particularly applies for the use of acids or abrasive cleaners (it is vital to read and observe the directions of the cleaning agent producer!).

### Note for L-Line Memory Micro Instruments

L-Line Memory Micro Instruments have been designed to offer to the user the best possible view over the surgery field. By bending the memory shaft the jaw parts can be placed in almost every position. After sterilization the memory shaft turns back into its original bayonet condition.

### Memory Shaft

The memory shaft should be held with both hands in the area where the bending is required.



- Bend the shaft of the L-Line Memory Instruments using only your hands. When doing so, do not exceed a bend angle of 90°.

- Do not bend the memory shaft by 90° more than 10 times during one operation.



**Do not bend the memory shaft at the connection areas of the start of the shaft or the jaw part. There is an increased risk of breakage.**



After sterilization the memory shaft turns back into original bayonet condition.

**Note: In order to return the shaft to its original shape, a minimum temperature of 70 °C is required.**

### **Preparation (cleaning, disinfection and sterilization)**

#### **General basics**

All instruments are delivered in non-sterile condition and must be cleaned, disinfected and sterilized before use (cleaning and disinfection after removing the transport protection packing (including jaw protection) and sterilization after packaging). Effective cleaning and disinfection is an essential requirement for effective sterilization.

As you are responsible for the sterility of the instruments during use, please ensure

- that only sufficiently device- and product-specifically validated procedures are used for the cleaning/disinfection and sterilization.
- that the used devices (disinfector, sterilizer) are maintained and checked on a regular basis and
- that the validated parameters are complied with in every cycle.

Please ensure already during the use to collect contaminated instruments separately and do not put them back into the instruments tray in order to avoid stronger contamination of the equipped instruments tray. Clean/disinfect the contaminated instruments, subsequently sort them back into the instruments tray and then sterilize the completely equipped instruments tray.

Please also comply with the legal regulations applicable in your country and the doctor's practice/hospital's sanitation regulations. This applies in particular to the different specifications regarding effective prion inactivation.



**The jaw protection serves only for protection during transport and sterilization; cleaning/disinfection with the jaw protection on is not permissible in any case.**

### **Cleaning and disinfection**

#### **Basics**

If possible, a machine procedure (disinfector) should be used for cleaning and disinfection. Due to the significantly lower effectiveness and reproducibility, a manual procedure – even when an ultrasound bath is employed – may only be used if no machine procedure is available.

The pre-treatment must be performed in both cases.

#### **Pre-treatment**

Major contaminations must be removed from the instruments immediately after use (within a maximum of 2 hours). Remove the jaw protection, unlatch the grip spring, if required, and bring the instrument into an opened position.

Use running water or a disinfectant solution for that; the disinfectant should be aldehyde-free (otherwise, blood contaminations would be preserved) and have proven efficacy (e.g. VAH/DGHM or FDA authorization or CE labeling), be suited for the disinfection of the microsurgical instruments and be compatible with the microsurgical instruments (see section "Resilience of the material"). Only use a soft brush or a clean soft cloth that you use only for this purpose, never metal brushes or steel wool, for manually removing contaminations.

If applicable:

Dismantle the instruments as far as possible and remove the jaw protection. Rinse all lumina of the instruments five times using a disposable syringe (minimum volume 10 mL).

Move the mobile parts forth and back several times during the pre-cleaning.

Please bear in mind that the disinfectant used during the pre-treatment is only for protection of persons and cannot act as a substitute for the disinfection step performed later (after the cleaning).

#### **Cleaning/disinfection using a device**

(disinfector / cleaning and disinfection device)

When selecting the disinfector, it must be ensured

- that the disinfectant always has proven efficacy (e.g. DGHM or FDA authorization or CE labeling according to DIN EN ISO 15883),
- that – if possible – a tested program for thermal disinfection (A0-value > 3000 or – for older devices – at least 5 min at 90 °C) is used (if chemical disinfection is used, there is the risk of residues of the disinfectant on the instruments),
- that the used program is suited for microsurgical instruments and contains sufficient rinsing cycles,
- that only sterile or low-germ (NMT 10 germs/mL) and low-endotoxin (NMT 0.25 endotoxin units/mL) water (e.g. purified water/highly purified water) is used,
- that the air used for drying is filtered and
- that the disinfectant is maintained and checked on a regular basis.

When selecting the cleaning agent system used, it must be ensured

- that it is generally suited for cleaning microsurgical instruments made of metals and plastics,
- that – unless thermal disinfection is used – a suited disinfectant with proven efficacy (e.g. DGHM or FDA authorization or CE labeling) is additionally used and that it is compatible with the cleaning agent used and
- that the chemicals used are compatible with the instruments (see section “Resilience of the material”).

The concentrations specified by the manufacturer of the cleaning agent/disinfectant must in any case be complied with.

#### **Procedure:**

1. Put the dismantled instrument into the disinfectant. Please ensure that the instruments do not touch each other. Place the instruments in opened position (it may be required to unlatch the grip-spring for this). If applicable: Connect all lumina of the instruments to the rinsing connector of the disinfectant.
2. Start the program.
3. Take the instruments out of the disinfectant after the program is finished.
4. Check and package the instruments as quickly as possible after taking them out (see the sections “Checking” and “Packaging”), if appropriate after additionally drying at a clean place.

The general suitability of the instruments for effective cleaning and disinfection using a machine was confirmed by an independent certified test laboratory using the disinfectant G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent Neodisher mediclean (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account in doing so.

#### **Manual cleaning and disinfection**

When selecting the cleaning agent and disinfectant used, it must be ensured

- that they are generally suited for cleaning / disinfecting instruments from metals and plastics,
- that the cleaning agent – if applicable – is suited for ultrasound cleaning (no formation of foam),
- that a disinfectant with proven efficacy (e.g. VAH/DGHM or FDA authorization or CE labeling) is used and that it is compatible with the cleaning agent used and
- that the chemicals used are compatible with the instruments (see section “Resilience of the material”).

Combined cleaning agents/disinfectants should not be used, if possible. Combined cleaning agents/disinfectants can only be used in cases of very slight contamination (no visible contaminations).

The concentrations and contact times specified by the manufacturer of the cleaning agent/disinfectant must in any case be complied with. Use only freshly-made solutions, only sterile or low-germ (NMT 10 germs/mL) and low-endotoxin (NMT 0.25 endotoxin units/mL) water (e.g. purified water/ highly purified water) and only filtered air for drying.

#### **Procedure: Cleaning**

1. Dismantle the microsurgical instruments as far as possible.
2. Put the dismantled instruments into the cleaning bath for the specified contact time such that the instruments are sufficiently covered (use ultrasound support or a soft brush, if appropriate). Please ensure that the instruments do not touch each other.  
If applicable: Rinse all lumina of the microsurgical instruments at least five times at the beginning and the end of the contact time using a disposable syringe (minimum volume 10 mL). Move all movable parts at least five times at the beginning and the end of the contact time back and forth.
3. Take the instruments out of the cleaning bath then and thoroughly rinse them off for at least 1 min under running water.  
If applicable: Rinse all lumina of the microsurgical instruments five times using a disposable syringe (minimum volume 10 mL).
4. Check all instruments (see section “Checking” and “Maintenance”).

#### **Disinfection**

5. Put the dismantled, cleaned and checked microsurgical instruments into the disinfection bath for the specified contact time such that the instruments are sufficiently covered. Please ensure that the instruments do not touch each other.  
If applicable: Rinse all lumina of the microsurgical instruments at least five times at the beginning and the end of the contact time using a disposable syringe (minimum volume 10 mL).  
Move all movable parts at least five times at the beginning and the end of the contact time back and forth.
6. Take the instruments out of the disinfection bath and thoroughly rinse them off for at least 1 min under running water.  
If applicable: Rinse all lumina of the instruments five times using a disposable syringe (minimum volume 10 mL).
7. Dry the instruments by blowing filtered compressed air.
8. Package the microsurgical instruments as quickly as possible after taking them out (see section “Packaging”, if required, after letting them dry in a clean place).

The general suitability of the instruments for effective manual cleaning and disinfection was confirmed by an independent certified test laboratory using the cleaning agent Cidezyme/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

### Control

Check all instruments after cleaning or cleaning/disinfection for corrosion, damaged surfaces, splitting and contaminations and discard damaged instruments (please refer to the section "Re-usability" for re-use limitation in numbers). Instruments that are still contaminated must be cleaned and disinfected again.

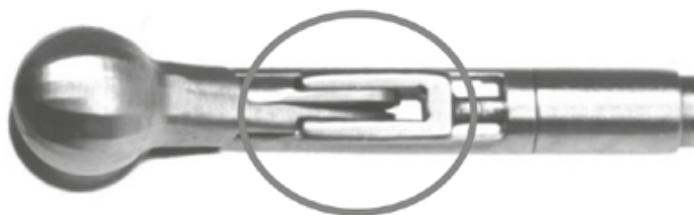
 **Disposal**  
**Risk of infection/microbiological hazards from contaminated products (e.g. blood). Beware of sharp edges.**

Prior to disposal, the devices must be cleaned and sterilized. The devices, packaging material and accessories should be disposed of in accordance with the valid country-specific laws and regulations.

### Maintenance

Note for instruments with joint (especially L-Line Memory Micro Instruments)

· Treat the joints of the Memory Instruments with instrument oil after every preparation. It should be ensured that only instrument oils (white oil) that – taking into account the maximum sterilization temperature used – are authorized for vapor sterilization and have proven biocompatibility, are used and that the jaw and joint parts are only treated with as little oil as possible.



- Discard outworn, corroded, deformed, porous or otherwise damaged Instruments
- Instruments which are sent in for repair works must be prepared completely for sanitary reasons.

### Packaging

Sort the cleaned and disinfected instruments into the corresponding sterilization tray.

Please package the instruments or trays in disposable sterilization packs (single or double pack) and/or sterilization containers that comply with the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suited for vapor sterilization (temperature resistance up to NLT 141 °C (286°F), sufficient vapor permeability)
- sufficient protection of the instruments / sterilization packs against mechanical damage
- regular maintenance in accordance with the manufacturer's specifications (sterilization container)

### Sterilization

Only the sterilization procedures listed in the following shall be used for sterilization; other sterilization procedures are impermissible.

Vapor sterilization

- fractionated vacuum procedure (with sufficient drying of the product)
- Vapor sterilizer in compliance with DIN EN 13060 / DIN EN 285
- Validated according to DIN EN ISO 17665 ((valid IQ/OQ consignment) and product-specific performance qualification)
- Maximum sterilization temperature 138 °C (280 °F; plus tolerance according to DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature) NLT 20 min at 121 °C (250 °F) or NLT 3 min at 132 °C (270 °F)/134 °C (273 °F)

The general suitability of the instruments for effective vapor sterilization was confirmed by an independent certified test laboratory using the vapor sterilizer Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg) and the fractionated vacuum procedure. Typical conditions in hospitals and doctor's offices as well as the procedure described above were taken into account in doing so.

 **Flash sterilization is never permissible.**  
**Do not use hot air sterilization, radiosterilization, formaldehyde or ethylene oxide sterilization and plasma sterilization, either.**

### Storage

Do not store the instruments in metal containers, except for stainless steel or aluminum containers. Avoid direct exposure to sunlight. After the sterilization, the instruments must be stored dry and free from dust in the sterilization pack.

### Resilience of the material

When selecting the cleaning agents and disinfectants, please ensure that they do not contain the following components:

- organic, mineral and oxidizing acids (minimum permissible pH value 5.5)
- strong lye (maximum permissible pH value 10.9, neutral/enzymatic or slightly alkaline cleaning agent recommended)
- organic solvents (e.g. alcohols, ether, ketones, benzene)

- oxidants (e.g. hydrogen peroxides)
- halogens (chlorine, iodine, bromine)
- aromatic/halogenated hydrocarbons

**Never clean any instruments and trays with metal brushes or steel wool.**


All instruments and trays may only be exposed to temperatures NMT 141°C (286 °F)!

#### Reusability

Based on the product design and the material used it is not possible to determine a precise limit with regard to the maximum number of reprocessing cycles. The serviceable life of the products is determined by their function as well as careful handling.










#### Repairs / shipping to Peter Lazic GmbH for repairs

In order to guarantee their proper functioning, any faulty must be sent to Peter Lazic GmbH. Do not carry out repairs yourself. Contact the manufacturer with any related questions.

 **Attention: Before being returned for repairs, faulty devices must have undergone the entire reprocessing process in accordance with the described reprocessing instructions. The corresponding declaration or proof of cleaning, disinfection and sterilization should be enclosed with the return.**

**Peter Lazic GmbH does not provide any warranty for Microsurgical Instruments which are handled contrary to the procedure / instructions for use recommended here.**

#### Figures and explanations

	Consult instructions for use
	Catalogue number
	Batch code
	Non-sterile
	CE-sign and shortcut of our Notified Body DQS GmbH / Frankfurt / Germany
	Manufacturer
	Date of production
<b>Rx only</b>	U.S. federal law restricts this device to be sold by or on the order of a physician only.
	Medical Device
	Caution

#### Manufacturer

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