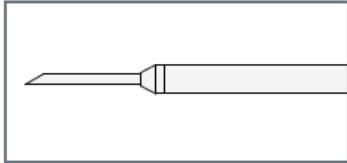


**Puncture needle**



**Item numbers:**

LP312-140	LP313-012	LP313-013
LP313-014	LP313-015	RU 0361-50/12
RU 0361-50/13	RU 0361-50/14	RU 0361-50/15

**Safety and responsibility**

Before you use the instrument  
-Read and follow these instructions.  
-Keep them available for future use in a clearly visible place.

Rudolf Medical accept no liability for consequences arising from improper use or improper processing and care. The warranty shall be null and void in such cases.

**Indication**

The instrument is intended for use in minimally invasive surgery, especially in laparoscopy. It can be used for the following surgical procedures:

- Puncturing the surgical site to introduce contrast media
- Puncturing cysts
- Taking biopsies

**Contraindication**

The instrument is not intended to be used on the central nervous system or the circulatory system.

**Risk of infection**

-Prepare the instrument before use.  
-Process the instrument before returning to the manufacturer.

**Risk of injury**

-Use only original accessories.  
-Do not use and do not repair damaged.  
-Take care when removing from the packaging.  
-Do not touch sharp edges

**Delivery contents**

-After unpacking, check the instrument for shipping damage.  
-Contact the manufacturer if there are any problems.

**Product description**

The puncture needle enables the introduction of contrast media into the surgical site. The contrast media can be introduced via an LL connection.



1 Needle  
2 LL connection

**Technical data**

Description	Value
Temperature	-30 °C -/+40°C
Relative humidity	≤ 90%
Air pressure	700-1200 hPa

Useful life of the product  
≤100 cycles and ≤2 years

**Before use**

Use components which are designed to be used with each other.

**Preparing for surgery**

**WARNING**  
Risk of infection from unsterile instruments.

- Prepare the instrument before use.  
Make an incision.
- Perform surgery
- Prepare the instrument

(See page 2-7)

**Safety information and explanation of symbols**

	Follow the instructions for use
<b>REF</b>	Order number
	Non sterile
	Manufacturer
<b>LOT</b>	Lot-Number
	CE marking with notified body number
	Caution! Failure to observe the warnings and precautions can lead to death or serious injuries.

**Overview of preparation methods**

**1 Safety and responsibility**

Before preparing instruments

- ▶ Read and follow the preparation instructions.
- ▶ Keep these instructions in a place where they can be easily seen for reference at a later date.

RUDOLF does not assume any liability for damage as a result of incorrect preparation and care. The user is responsible for validating alternative cleaning and sterilisation methods.

The specified procedures for manual and mechanical reprocessing are validated by the manufacturer. These procedures are recommendations. Any modification by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

**Risk of infection**

- ▶ Prepare the instrument before use.
- ▶ Prepare the instrument before returning it to the manufacturer.
- ▶ Follow the instructions for use of the cleaning agents and disinfectants used as well as of the cleaning and sterilization devices used.

- ▶ Wear gloves during preparation.
- ▶ Discard disposable components after initial use.

**Risk of injury**

- ▶ Do **not** use damaged instruments and do **not** repair
- ▶ Only use original accessories.

**2 Explanation of symbols**

- DANGER**  
Indicates a danger which results in death or serious injury if not avoided.
- WARNING**  
Indicates a danger which can result in death or serious injury if not avoided.
- CAUTION**  
Indicates a danger which can result in injuries if not avoided.

- IMPORTANT!**  
Indicates measures in order to prevent damage to property.

- This symbol provides information in order to facilitate handling of the device.
  - ▶ Here measures are given which must be followed to prevent a risk.
  - ▶ You are requested to take action here.
  - ↳ You find out the result of the action taken here.
  - ↗ This symbol indicates additional information.
- TIP:  
The „TIP“ provides useful advice on handling the instrument.

**3 Preparing decontamination**

To prevent surgical residue from drying on, the following steps must be performed **directly after surgery**.

- CAUTION**  
Risk of infection due to the fixation of residues.
  - ▶ Rinse of infection due to the fixation of residues.
  - ▶ Remove coarse dirt with cold water.

Puncture Needle

- ▶ Rinse out cavities with cold water.



If it is not possible to rinse with cold water, the instrument must be wrapped in a moist cloth to prevent any residues from drying on.

- ▶ Always transport the instrument to the preparation site in a closed container to prevent product damage and contamination of the environment.

**4 Pre-cleaning**

Pre-cleaning prevents germs from spreading and surgical residue from drying on. It must therefore be carried out **directly after surgery**.

Pre-cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert:

Cleaning	Dosage	pH value
Alkaline	0.5 %	11.4-11.9 (diluted)



**WARNING**

Risk of infection and pyrogenicity if unsuitable cleaning agents are used.

- ▲ Do not use fixing agents.
- ▲ Do not rinse with hot water.

**IMPORTANT!** Avoid damaging product.

- ▲ Do not use abrasive brushes or scourers.
- ▲ Only use suitable cleaning agents.
- ▲ Use disinfectant with corrosion protection.



Rinse the instrument below the water level. This prevents the spread of germs.

- ▶ Place the instrument in cold water: >5 min.
- ▶ Dismantle the instrument (if possible).
- ↗ See instrument's instructions for use.
- ▶ Open stop cocks (if relevant).

**TIP:**

- Remove caked-on tissue residues with a plastic brush.
- ▶ Brush the outside and inside under cold water with a round brush until no more residue is visible.
- ▶ Rinse out cavities, drill holes and threads (if relevant) with a cleaning gun: > 10 s at 3-5 bar.
- ▶ Remove from the water bath and rinse off with cold water.

- ▶ Immerse in combined cleaning and disinfectant solution until subsequent cleaning to prevent any residue from drying on.

**5 Cleaning**

Unless stated otherwise in the instrument's Instructions for Use, cleaning is performed with the instrument disassembled.

Cleaning was validated with the cleaning agent Neodisher FA from Dr. Weigert:

Cleaning	Dosage	pH value
Alkaline	0.5%	11.4-11.9 (diluted)



**WARNING**

Risk of infection due to insufficient preparation.

- ▲ Remove protective caps (if relevant).

**IMPORTANT!** Avoid damaging product.

- ▲ Only use suitable cleaning agents.
- ▲ Avoid contact with hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>).
- ▲ Do not use abrasive brushes or scourers.
- ▶ Choose between manual and mechanical cleaning.

**5.1 Manual**



Rinse the instrument below the water level. This prevents the spread of germs.

- ▶ Open stop cocks (if relevant).



Additionally clean the components in an ultrasonic bath with the following settings:

Temperature	Frequency	Duration
40°C	35-45 kHz	>4 min

Turn and move the components several times during cleaning in the ultrasonic bath.

- ▶ Clean the inner chambers with a cleaning brush below water.
- ▶ Rinse through the inner chambers with a cleaning agent: 3-20 min. at 45-85 °C
- ▶ Immerse the instrument in cold demineralised water and rinse through the cavities several times with demineralised water.

**Disinfect and dry**

Disinfection was validated with the disinfectant Cidex OPA from Johnson & Johnson:

Cleaning	Dosage	pH-value
Alkaline	0.5 %	7.2 – 7.8 (diluted)

- ▶ Disinfect with disinfectant.
  - ↗ See manufacturer's Instructions for use.
- ▶ Dry on the inside and outside: >10 min at 50-100 °C  
And/or:  
Blow through with sterile compressed air.

**5.2 Mechanical**

Mechanical cleaning was validated with the cleaning device 7735 CD and 7736 CD from Miele. Proper cleaning depends on the right cleaning program. Compare the cleaning program with that of your cleaning system and save where necessary:

1. Pre-rinse with cold water: 1 min.
2. Empty
3. Repeated pre-rinsing with cold water: 3 min.
4. Empty
5. Clean with 0.5 % mild alkaline
6. Empty
7. Neutralise with warm tap water and a suitable neutraliser: 3 min. at >40°C
8. Empty
9. Rinse with warm tap water: 2 min. at >40 °C
10. Empty
11. Disinfect: Observe the national requirements as regards the A0 value (see ISO 15883)
12. Dry: 15-25 min. at 90°-110°C

- ▶ Open stop cocks (if relevant).
- ▶ Place instruments in a sieve tray on the MIC cleaning device trolley so that the cleaning agent can reach all inner and outer surfaces.
- ▶ Connect the flush port (if relevant) to the MIC cleaning device trolley.
- ▶ Start the cleaning program
- ▶ If necessary, additionally dry the instrument after cleaning with sterile compressed air.



Additionally clean the components in an ultrasonic bath with the following settings:

Temperature	Frequency	Duration
40 °C	35-45 kHz	>4 Min

Turn the components over several times during cleaning in the ultrasonic bath.

**6 Care**

Caring for the instruments properly will lengthen their service life and should therefore be carried out after every cleaning process.



**WARNING**

Risk of injury from faulty or damaged components

- ▲ Do not reuse faulty or damaged instruments.
- ▶ Check to ensure they are clean and if necessary, repeat cleaning.
- ▶ Check for damage (e.g., sharp edges, rough surfaces).
- ▶ Replace brittle and cracked seals (if relevant).
- ▶ Lubricate moving parts (e.g., joints rotating stop cocks) with medical oil.
- ▶ Remove any excess oil.
- ▶ Do not use damaged components.
- ▶ Assemble instruments (if possible) and check to ensure they are in perfect working order.
  - ↗ See instrument's Instructions for use.

**7 Wipe-down disinfection**

Wipe-down disinfection serves to reduce the germs on the surfaces of devices. Wipe-down disinfection was validated with the wipe-down disinfectant Neoform MED AF from Dr. Weigert:

Dosage	Exposure time
1 %	15 min.
2 %	5 min.



**IMPORTANT!** Avoid damaging product.

- ▲ Do not use abrasive brushes or scourers.
- ▲ Use a suitable disinfectant.
- ▶ Wipe down the device surface with a wipe-down disinfectant.

**8 Packaging**

The instrument must be packaged appropriately to prevent recontamination with the environment.

- ↗ Appropriate packaging for sterilization according ISO 11607 and EN 868.

**9 Sterilising**

Unless stated otherwise in the instrument's Instructions for Use, sterilisation is performed with the instrument assembled.

- ↗ You will find detailed information on the assembly of the instrument in the latter's Instructions for Use.

Sterilisation was validated with the sterilisation device Selectomat S 3000 from MMM Group and Variocalv 400 E from Fisher Scientific.

**IMPORTANT!** Avoid damaging product.

- ▲ Observe the device's maximum load.
- ↗ See manufacturer's Instructions for Use.



**WARNING**

Risk of infection due to excessively short sterilisation time.

- ▲ If there is a suspicion of prions and Creutzfeldt-Jakob disease, the sterilisation time must be  $\geq$  18 min.

The sterilisation time is between 4-30 min. The following countries make different stipulations which must be observed:

Country	Sterilisation time
France	$\geq$ 18 min.
Switzerland	$\geq$ 18 min.

- ▶ Open stop cocks (if relevant).
- ▶ Place in the sterilisation device so that the components are not touching each other and the steam can circulate freely.
- ▶ Select sterilisation parameters:

Temperature	Pressure	Duration
134-137 °C	3 bar 44 psi	↗ See details in this chapter.

- ▶ Start the sterilisation process.

**10 Storing sterile devices**

To prevent reducing durability and forfeiting any resistance to bacteria, the following storage conditions must be observed:

- ▶ Store the sterile device sealed in a clean, dust-free and dry sterile container.
- ▶ Store the sterile container in a clean and dry environment with controlled humidity at room temperature.
- ▶ Do **not** store the sterile container in the vicinity of aggressive substances (e.g., alcohols, acids, bases, solvents and disinfectants).



Also observe your internal storage standards for sterile devices.

**11 Disposal**



Environmentally sound disposal enables valuable raw materials to be recycled. Dispose of the device in an environmentally friendly manner in accordance with the valid hospital guidelines.

**12 Information on validation**

The following materials and machines were used for validation:

- Cleaning agent: Neodisher FA from Dr. Weigert.
- Cleaning and disinfection device: 7735 CD and 7736 CD from Miele.
- Sterilisation device: Selectomat S 3000 from MMM Group and Variocalv 400 E from Fisher Scientific
- Sterilizing agent: Moist heat

**Processing**

Preparation methods	Preparation agents	Re-usable surgical instruments	Instruments for use with endoscopes	
Pre-clean directly after use	Wet	Soften in cleaning and disinfectant solution and rinse with water	++	
	Dry	Wipe with a moist cloth or with cleaning and disinfectant solution	+	
Decontaminate	Pre-clean*	See chapter 4 Preparing decontamination		
	Clean*	Manual <sup>1</sup>	++	+
		Mechanical <sup>1</sup>	++	+
		Ultrasound	+	+
	Alkaline cleaning agent <sup>5</sup> pH 9-12		++	++3
			55-85 °C/ 3-20 min.	55-85 °C/ 3-20 min.
		Acid cleaning agent <sup>5</sup>	++	++ <sup>3</sup>
	Neutral cleaning agent <sup>5</sup>		55-85 °C/ 3-20 min.	55-85 °C/ 3-20 min.
			++	++ <sup>3</sup>
	Enzymatic cleaning agent <sup>5</sup>		55-85 °C/ 3-20 min.	55-85 °C / 3-20 min.
			+	+
	Rinse	Demineralsed water	+	+
	Disinfect	Chemically up to max. 60 °C	-	+
		Thermally up to max. 93 °C	+	+
Dry	Temperature	++	++	
		50-100 °C/ >10 min.	50-100°C/ >10 min.	
Care <sup>6</sup>	See chapter 6 Cleaning.	++	++	
Sterilise <sup>7</sup>	Moist heat, autoclave, prevacuum	++	++	
		134-137 °C	134-137 °C	
	Low temperature (steam+formaldehyde)	+	+	
	Ethylene oxide	+	+	
	Hot air	-	-	
	Liquid sterilant	+	+	
	Gas plasma	-	-	

Symbol	Explanation
++	Method with validated microbiological effectiveness and verified material compatibility
+	Method with verified material compatibility
-	Incompatibility
0	For further information contact the manufacturer
#	For more detailed information see chapter "6 Cleaning"
<p>1 Deionized water is recommended for final rinsing.</p> <p>2 Rubber and/or latex, silicone elastomers.</p> <p>3 Does not apply to (anodised) aluminium alloys.</p> <p>4 Not suitable for ultrasonic-assisted cleaning.</p> <p>5 Follow the cleaning agent's Instructions for Use.</p> <p>6 ↗For detailed information see chapter „7 Care“.</p> <p>7 ↗Duration of sterilisationsee chapter „9 Packaging“ on page</p>	
<p><b>i</b> More detailed information on preparation is available from Robert Koch-Institut (RKI) and the Instrument Preparation Working Group (AKI): RKI: Hygiene Requirements for Reprocessing Medical Devices (edition 01.11.2001, www.rki.de) AKI: Proper Maintenance of Instruments (edition 8, www.a-k-i.org)</p>	