Percutaneous Low Pressure Universal Nephroscope

8962.xxx
8972.xxx
Important general notes and instructions for use

Make sure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified medical personnel, and that maintenance and repair are only carried out by authorized experts.

Use the product only in the combinations and with the accessories and spare parts specified in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for the planned application and if the performance characteristics and safety requirements are met. The product must not be altered in any way.

Reprocess the products in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

Immediately upon receipt, check the product and its accessories for completeness and possible damage. Should the shipment give right to complaints, please inform the manufacturer or supplier immediately.

Subject to technical changes!
Due to ongoing developments, the illustrations and technical data may deviate slightly.

CAUTION:
Federal law restricts this device to sale by or on the order of a physician.

Safety instructions and levels of danger

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Level of danger</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>WARNING! Failure to observe can result in death or serious injury.</td>
</tr>
<tr>
<td>!</td>
<td>CAUTION! Failure to observe can result in slight injury or damage to the product.</td>
</tr>
<tr>
<td>!</td>
<td>IMPORTANT! Failure to observe can result in damage to the product or surroundings.</td>
</tr>
<tr>
<td>!</td>
<td>NOTE! Tips for optimum use and other useful information.</td>
</tr>
</tbody>
</table>

USA
RICHARD WOLF
Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061
Toll Free: 001 (800) 323 - 9853
Phone: 001 (847) 913 - 1113
Fax: 001 (847) 913 - 1488
MANUFACTURER
sales@richardwolfusa.com
www.richardwolfusa.com

GERMANY
RICHARD WOLF GmbH
75438 Knittlingen
Pforzheimerstr. 32
Telephone: +49 70 43 35-0
Telefax: +49 70 43 35-300
info@richard-wolf.com
www.richard-wolf.com

UK
RICHARD WOLF UK Ltd.
Waterside Way
Wimbledon
SW17 0HB
Telephone: + 44 20 89 44 74 47
Telefax: +4 44 20 89 44 13 11
admin@richardwolf.uk.com
www.richardwolf.uk.com

BELGIUM / NETHERLANDS
N.V. Endoscopie
RICHARD WOLF Belgium S.A.
Industriezone Drongen
Landegemstraat 6
9031 Gent Drongen
Telephone: +32 92 80 81 00
Telefax: +32 92 82 92 16
endoscopy@richard-wolf.be
www.richard-wolf.be

FRANCE
RICHARD WOLF France S.A.R.L.
Rue Daniel Berger
Z.A.C. La Neuvillette
F-51100 Reims
Telephone: +33 3 26 87 02 89
Telefax: +33 3 26 87 60 33
france@richard-wolf.com

AUSTRIA
RICHARD WOLF Austria
Ges.m.b.H.
Wilhelminenstraße 93 a
A-1160 Vienna
Telephone: +43 14 05 51 51
Telefax: +43 14 05 51 51 45
austria@richard-wolf.com
www.richard-wolf.com

INDIA
RICHARD WOLF India Private Ltd.
JMD Pacific Square
No. 211 A, Second Floor
Behind 32nd Milestone
Gurgaon - 122 001
National Capitol Region
Telephone: + 91 12 44 31 57 00
Telefax: + 91 12 44 31 57 05
india@richard-wolf.com
www.richard-wolf.com

Marketing Office
U.A.E
RICHARD WOLF Middle East
P.O. Box 500283
AL Thuraya Tower 1
9th Floor,
Room 904, Dubai
Telephone: + 9 71 43 68 19 20
Telefax: + 9 71 43 68 61 12
middle.east@richard-wolf.com
www.richard-wolf.com
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1 Intended use
Nephroscope with suitable Richard Wolf auxiliary instruments are used e.g. for
the disintegration and removal/aspiration of kidney and bladder stones as well as
for the removal of tumors via a percutaneous or transurethral passage in con-
junction with intracorporeal lithotripters, e.g. operated pneumatically, by ultra-
sound, electrohydraulically or by laser under endoscopic control.

2 Indications and field of use
For the diagnosis and therapy of diseases such as urolithiasis or stenoses and
tumors in conjunction with endoscopic accessories in the upper and lower uro-
genital tract.
The products may only be used by adequately qualified and trained medical per-
sonnel.

3 Contraindications
Contraindications directly related to the product are presently unknown.
On the basis of the patient's general condition the physician/surgeon in charge
must decide whether the planned use is possible or not. For further information
see the latest medical literature.

4 Combinations
- Intracorporeal lithotripsy systems (e.g. ultrasonic, EHL, etc.)
- Suction and irrigation devices
- Light sources and flexible light cables
- Video cameras and objective lenses
- Endoscopic accessories:
  - Grasping forceps, stone extractors, stricture scalpels, transducers, sonotrodes,
  - probes and laser fibers.

⚠️ CAUTION!
Caution if products are incorrectly combined!
Possible injury of the patient, user or others as well as possible damage to the
product.

Different products should only be used in combination if their intended uses and
relevant technical data (working length, diameter, etc.) are the same.

Follow the instruction manuals of the products used in conjunction with this
product.

The cold-light connector (1.2) can be unscrewed and replaced by suitable ad-
aptors to connect flexible light cables of other manufacturers.
For the order number please refer to the latest catalog sheet.
### 5.1 Legend and identification

<table>
<thead>
<tr>
<th>Item</th>
<th>Designation</th>
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<tbody>
<tr>
<td>1</td>
<td>Nephroscope</td>
<td>2</td>
<td>Operation sheath</td>
</tr>
<tr>
<td>1.1</td>
<td>Sheath tube</td>
<td>2.1</td>
<td>Suction holes</td>
</tr>
<tr>
<td>1.2</td>
<td>Cold-light connector</td>
<td>2.2</td>
<td>Drain stopcock</td>
</tr>
<tr>
<td>1.3</td>
<td>Irrigation stopcock</td>
<td>2.3</td>
<td>Locking lever</td>
</tr>
<tr>
<td>1.4</td>
<td>Port stopcock (for insertion)</td>
<td>2.4</td>
<td>Screw ring</td>
</tr>
<tr>
<td>1.5</td>
<td>Sealing cap</td>
<td>3</td>
<td>Obturator</td>
</tr>
<tr>
<td>1.6</td>
<td>Eyepiece with eye cup</td>
<td>3.1</td>
<td>Central bore for guide wire</td>
</tr>
<tr>
<td>1.7</td>
<td>Colored coding ring red:</td>
<td>4</td>
<td>Internal sheath</td>
</tr>
<tr>
<td></td>
<td>Direction of view 25°</td>
<td>4.1</td>
<td>Distal insulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2</td>
<td>Irrigation stopcock</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.3</td>
<td>Locking lever</td>
</tr>
</tbody>
</table>

Identification in conformity with Medical Devices Directive 93/42/EEC only valid if the product and/or packaging is marked with this symbol. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code number of the notified body (0124).
6 Use

⚠️ CAUTION!
The products have only limited strength!
Exerting excessive force will cause damage, impair the function and therefore endanger the patient.
Immediately before and after each use, check the products for damage, loose parts and completeness.
Ensure that no missing instrument parts remain in the patient.
Do not use products which are damaged, incomplete or have loose parts.

6.1 Preparation

- Perform a visual check: section 7 and 7.1
- Attach sealing cap (1.5).

6.1.1 Inserting obturator (3) into operating sheath (2)

**Locking:**
- The locking lever (2.3) is in position "I" (12 o'clock position)
- Insert the obturator (3) into the operating sheath (2).
- The pin (b) must engage in groove (a)
- Turn the locking lever (2.3) to position "II" (2 o'clock position).

![Fig. 1](image)

**Unlocking:**
- Turn the locking lever (2.3) to position "I" (12 o'clock position), remove the obturator (3).

6.1.2 Inserting nephroscope (1) into operating sheath (2)

**Locking:**
- The locking lever (2.3) is in position "I" (12 o'clock position)
- Insert the nephroscope (1) into the operating sheath (2).
- The pin (b) must engage in the groove (a).
- Turn the locking lever (2.3) to position "II" (2 o'clock position).

![Fig. 2](image)

**Unlocking:**
- Turn the locking lever (2.3) to "I" (12 o'clock position) and remove the nephroscope (1).
Connect the supply lines (light, irrigation, drain, video)

Carry out a function check.

After the necessary orientation and a view of the objects to be treated, insert the corresponding auxiliary instrument (e.g. lithotripsy probes, grasping forceps, etc.).

6.2 Additional notes and indications for use

In the case of percutaneous use, puncture the hollow organ with a conventional puncture set if this hasn’t been done before, and dilate to the corresponding internal diameter (24 Fr. or larger) of the operating sheath (2). Remove the dilators except for the guide wire.

Place the operating sheath (2) without the obturator (3) over the 24 Fr. telescope dilator

or:

insert the operating sheath (2) with obturator (3) via the guide wire into the hollow organ.

Carry out both procedures under x-ray control.

NOTE!

If an "Amplatz" sheath is used, the nephroscope (1) can be used directly, i.e. without operating sheath (2).
The water supply flows through the nephroscope. The Amplatz sheath represents the drain.

6.2.1 Light

IMPORTANT!

Use only products with type BF applied parts in conjunction with this endoscope.

CAUTION!

Heat accumulation due to high light energy!

In the case of unfavorable combinations, the use of high temperature-resistant flexible light cable 8063.35 can cause a temperature increase at the coupling point between the flexible light cable and the endoscope.

For the user this may result in burns and the endoscope may become damaged.

Reduce the light output, use flexible light cable product no. 8061.xx3 / 8062.xx3, if necessary.

WARNING!

Generation of heat due to high light energy!

Danger of inadvertent tissue damage due to insufficient distance between the light exit area and the tissue.

Do not touch the light exit area and avoid direct contact with the tissue.

WARNING!

Fire hazard!

The high temperatures generated at the light exit area cause excessive heating or even ignition when the endoscope is placed on heat-sensitive flammable surfaces (such as dark drapes etc.).

Always lay the endoscope down at a safe place.

If you do not use the endoscope for a prolonged period of time, switch off the light source.

6.2.2 Current

WARNING!

Danger of electric shock!

Patient leakage currents can add up, if endoscopes are combined with powered endoscopic accessories.

You should ensure that the combinations do not exceed the authorized patient leakage currents.
6.2.3 Irrigation fluid

\[\text{CAUTION}!\]

Caution when using electrically conductive irrigation fluid!
The use of such fluid will lead to inadvertent thermal tissue damage.
The user must select a low-conductivity irrigation fluid suitable for the purpose.

\[\text{CAUTION}!\]

Carry-over of irrigation fluid into vessels as a result of positive pressure!
Such carry-over will cause severe injury to the patient.
To ensure a low-pressure continuous irrigation effect, open drain stopcock (2.2) on operating sheath (2) while irrigation fluid is supplied.

6.2.4 HF application

Make sure you observe the "Instructions and notes on HF applications", order no.: GA-S 002 as well as the HF device manufacturer's instructions.

\[\text{WARNING}!\]

Danger of injury if the HF instrument is not visible through the scope!
Inadvertent tissue damage as well as damage to the distal end of the endoscope and parts of the instrument is possible.
Activate HF instruments only after the live part conducting HF current has become fully visible in the field of view of the endoscope and touches the intended area to be treated.

\[\text{WARNING}!\]

HF arcing!
Danger of injury from wrong HF application and insufficient distance between parts conducting HF current and other conductive parts.
During activation, parts of HF instruments conducting high frequency current must be at a safe distance of at least 10 mm from the distal end of the endoscope (Fig. 4).

6.2.5 Laser application

\[\text{CAUTION}!\]

Do not work outside the field of view!
Inadvertent tissue damage as well as damage to the distal end of the endoscope and parts of the instrument is possible!
Activate the laser only after the tip of the laser fiber has become fully visible in the field of view of the endoscope and touches the intended area to be treated.

\[\text{CAUTION}!\]

Accumulation of heat due to highly concentrated laser beam!
The heat generated by the laser beam can reduce the strength of instrument parts.
Do not aim the laser beam at instrument parts, in particular not at plastic parts.
Maintain adequate safety distance.

\[\text{CAUTION}!\]

Do not work without filter attachment! Danger of eye injuries!
Use a suitable filter attachment on the endoscope eyepiece.

6.3 Percutaneous tumor resection in the renal pelvis

The internal sheath (4) is used in conjunction with the operating sheath (2) to guarantee continuous irrigation.

\[\text{IMPORTANT!}\]

Preferably, working elements with passive cutting action (spring-assisted cutting) should be used to avoid injuries by projecting electrodes in the relatively narrow renal pelvis.
6.3.1 Procedure

**IMPORTANT!**

Follow the instruction manual for the resectoscope instrument set.
- Insert the electrode into the working element in accordance with the resectoscope manual.
- Introduce the telescope into the working element in accordance with the resectoscope manual.
- Introduce the pre-assembled working element into the internal sheath (4).

**Locking:**
- The locking lever (4.3) must be in "I" (12 o'clock position)
- Introduce the working element into the operating sheath (2).
- The pin (b) must engage in groove (a).
- Turn the locking lever (4.3) to "II" (2 o'clock position).

**Unlocking:**
- Turn the clamping lever (4.3) to position "I" (12 o'clock position), then remove the working element.

Fig. 5

- Introduce the complete instrument set into the operating sheath (2) already in situ.
- The locking lever (2.3) must be in position "I" (12 o'clock position)
- Introduce the complete pre-assembled internal sheath (4) into the operating sheath (2).
- The pin (c) must engage in groove (d).
- Turn the locking lever (2.3) to position "II" (2 o'clock position).

**Unlocking:**
- Turn the locking lever (2.3) to position "I" (12 o'clock position), the remove internal sheath (4).

Fig. 6
7 Checks

⚠️ CAUTION!
Be careful if products are damaged or incomplete!
Possible injury of patient, user or third persons.
Run through the checks before and after each use.
Do not use products which are damaged or incomplete or have loose parts.
Return damaged products together with loose parts for repair.
Do not attempt to do any repairs yourself.

7.1 Visual checks

- Check instruments and accessories for
  - damage
  - sharp edges
  - loose or missing parts
  - rough surfaces.
- Check the sealing cap (1.5) for damage and replace if necessary.
- Any lettering, labeling or identification necessary for the safe intended use
  must be legible.
- Missing or illegible lettering, labeling or identification which may lead to
  wrong handling and reprocessing must be restored.

7.2 Functional check

- Check the suction and irrigation flow before each use

7.2.1 Checking image quality and light output

- Any deposits on the glass surface can cause a stained or blurred field of view
  and may reduce the light transmission considerably.
- Wipe glass surfaces with a swab (wooden swab carrier, not metal or plastic)
  soaked with alcohol, wipe hard-to-remove deposits with instrument cleaner *
  For this, also refer to "Reprocessing of RICHARD WOLF Heat Stable Instruments",
  order no. GA-J 020.

*Fig. 7

- Hold the distal end of the endoscope towards a light source.
- Broken fibers appear as black dots on the cold-light connector (1.2). The
  light output is no longer sufficient if approx. 30% of the fibers are broken.
8 Reprocessing and maintenance

**IMPORTANT!**
Further notes and instructions on reprocessing are described in manual GA-J020 "Reprocessing of RICHARD WOLF Heat-Stable Instruments" and must be followed.

8.1 Disassembly before cleaning

8.1.1 Nephroscope (1)
- Remove the rubber cap (1.5).
- Unscrew the cold-light connector (1.2).

8.1.2 Operating sheath (2)
- Unscrew the screw ring (2.4) - LEFT-HAND THREAD - and remove.
- Remove the irrigation ring (2.5).
- Remove the sealing rings (2.6).

8.2 Manual reprocessing
- Wet preparation at the point of use
- Disassembly before cleaning: see section 8.1
- Manual cleaning / disinfection

8.3 Machine reprocessing
- Dry preparation at the point of use
- Disassembly before cleaning: see section 8.1
- Machine cleaning / disinfection

8.4 Checks
- Perform a visual check (see section 7.1)
8.5 Assembly before sterilization

NOTE!
Before sterilization screw on screw connections only loosely
• to allow a sufficient flow of the sterilization medium
Tighten all screw connections after sterilization and before use.

8.5.1 Assembly of nephroscope (1)
• Screw on the cold-light connector (1.2) only loosely.

8.5.2 Assembly of operating sheath (2)
• Install the sealing rings (2.6), moisten with instrument oil 200.532 if necessary.
• Install irrigation ring (2.5) as far as it will go.
• Screw on the screw ring (2.4) only loosely - LEFT-HAND THREAD

Fig. 10

8.6 Sterilization
8.6.1 Steam sterilization
• Steam sterilization at 132°C (270°F) using a Pre-Vac process/cycle at an exposure time of 4 minutes with a 20 minutes dry time.

8.6.2 Gas sterilization
• Gas sterilization using ethylene oxide (EtO).

8.6.3 Alternate Sterilization Methods
• For possible alternate sterilization methods, refer to our website, www.richardwolfusa.com under „Reprocessing & Sterilization“ for lists of Richard Wolf instruments that are approved for various reprocessing methods.
9 Technical data and order data

<table>
<thead>
<tr>
<th>Model/ type no.</th>
<th>Designation, Technical data</th>
</tr>
</thead>
</table>
| 8962.433       | PANOVIEV operating telescope  
Direction of view 25°; oval probe channel for 4 mm auxiliary instruments, working length 195 mm. |
| 8972.433       | PANOVIEV operating telescope with angled eyepiece  
Direction of view 25°; oval probe channel for 4 mm auxiliary instruments, working 195 mm |
| 8962.061       | Operating sheath consisting of: |
| 8962.065       | Operating sheath (2)  
27 Fr., working length 175 mm |
| 8962.067       | Obturator (3) |
| 8962.122       | Internal sheath, insulated distal end. |

10 Spare parts and accessories

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Model/ type no.</th>
<th>Designation, Technical data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8962.951</td>
<td>Stricture scalpel, crescent-shaped, 3,5 mm dia.</td>
</tr>
<tr>
<td></td>
<td>886.00</td>
<td>Luer lock tube fitting</td>
</tr>
<tr>
<td></td>
<td>88.01</td>
<td>Sealing cap (red-organ) (item 1.5)</td>
</tr>
<tr>
<td></td>
<td>8095.00</td>
<td>Cold-light connector (item 1.2)</td>
</tr>
</tbody>
</table>
|              | 6.03           | Cleaning brush  
Diameter 5 mm, length of brush 50 mm, total length 375 mm |
|              | 200.532        | Instrument oil (10 ml) |
|              | 15 364.068     | Sealing rings (item 2.6) for operating sheath (2) |

The products can be combined as required provided the relevant technical data and intended uses are observed. For the general overview please refer to the latest catalog sheets and brochures, or contact Richard Wolf or your Richard Wolf representative.

11 Operating, storage, transport and shipping conditions

| Operating conditions | +10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |
| Storage, transport and shipping conditions | - 20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa |

NOTE!  
To prevent damage during transport or shipment of the products we recommend using the original packaging material.

11.1 Disposal of product, packaging material and accessories

For the disposal observe the regulations and laws valid in your country.  
* For further information please contact the manufacturer.
**Warranty and Customer Service**

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser’s purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer’s representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

**INSTRUMENT ORDERING POLICY**

Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

**REPAIR POLICY**

Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

**REPAIR SHIPMENTS**

When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

**IMPORTANT**

For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $100.00 cleaning charge for each instrument requiring cleaning.