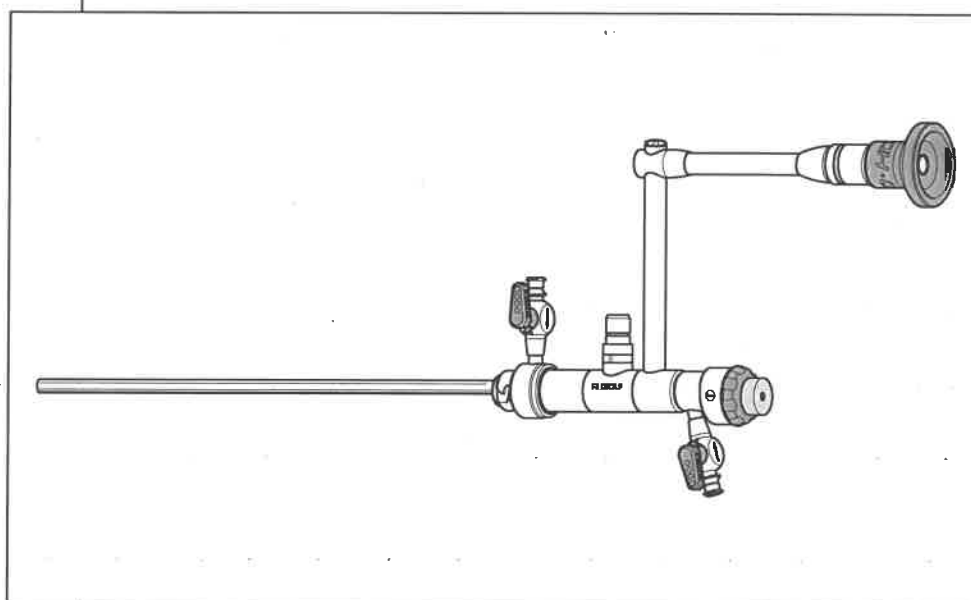


Instruction Manual



“Piranha Scope”

PANOVIEW OPERATING TELESCOPE

8970402

⚠ 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 is only carried out by authorized specialized technicians.

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.

Reprocess the products before every application and before returning them for repairs as required by the instruction manual in order to protect the patient, user or third parties.

Subject to technical changes!

Due to continuous development of our products, illustrations and technical data may deviate slightly from the data in this manual.

CAUTION :

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

Safety instructions and levels of danger

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

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1 Intended use

The "Piranha Scope" PANOVIEW Operating Telescope with the corresponding sheaths and obturators in conjunction with a morcellation probe, is used for morcellating and continuous removal of large tissue parts.

In addition, the telescope can be used as a nephroscope with the corresponding auxiliary instruments for disintegrating and removing / aspirating kidney and bladder stones and to remove tumors via percutaneous (kidney) or transurethral (bladder) access under endoscopic control, in conjunction with intracorporeal lithotripters e.g.: pneumatic, ultrasound, electro-hydraulic or laser lithotripters.

2 Indications and field of use

The product is used for therapy with transurethral access, in the case of diseases of the lower urinary tract e.g. laser TURP (TransUrethral Resection of the Prostate).

As a nephroscope it is used for diagnosis and therapy of urolithiasis and tumors in the upper and lower urogenital tracts.

In both cases it is used with endoscopic accessories.

This product may only be applied by adequately qualified and trained medical personnel.

3 Contraindications

Contraindications directly related to the product are currently unknown. On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not. For further notes and instructions please refer to the latest medical literature.

4 Combinations

The "Piranha Scope" PANOVIEW Operating Telescope is used in conjunction with:

- ◇ morcellation systems
- ◇ suction and irrigation devices
- ◇ light sources and flexible light cables
- ◇ video cameras and objective lenses

As a nephroscope the "Piranha Scope" PANOVIEW Operating Telescope is used in conjunction with:

- ◇ intracorporeal lithotripsy systems (e.g. ultrasound, EHL, etc.)
- ◇ suction and irrigation devices
- ◇ light sources and flexible light cables
- ◇ video cameras and objective lenses
- ◇ endoscopic accessories:
holding forceps, stone extractors, stricture scalpels, transducers, sonotrodes, probes, laser fibers.



CAUTION!

Do not combine products incorrectly!

Injuries of the patient, user or third parties as well as damage to the product are possible.

Combine the different products only if their intended uses and relevant technical data (working length, diameter, etc.) are the same.

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

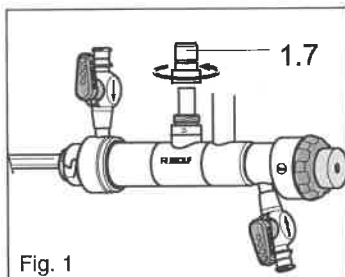


Fig. 1

The cold-light connector (1.7) can be unscrewed and replaced by corresponding adapters to connect flexible light cables by other manufacturers.

For the order no., please refer to the latest catalog sheet.

5 Illustration

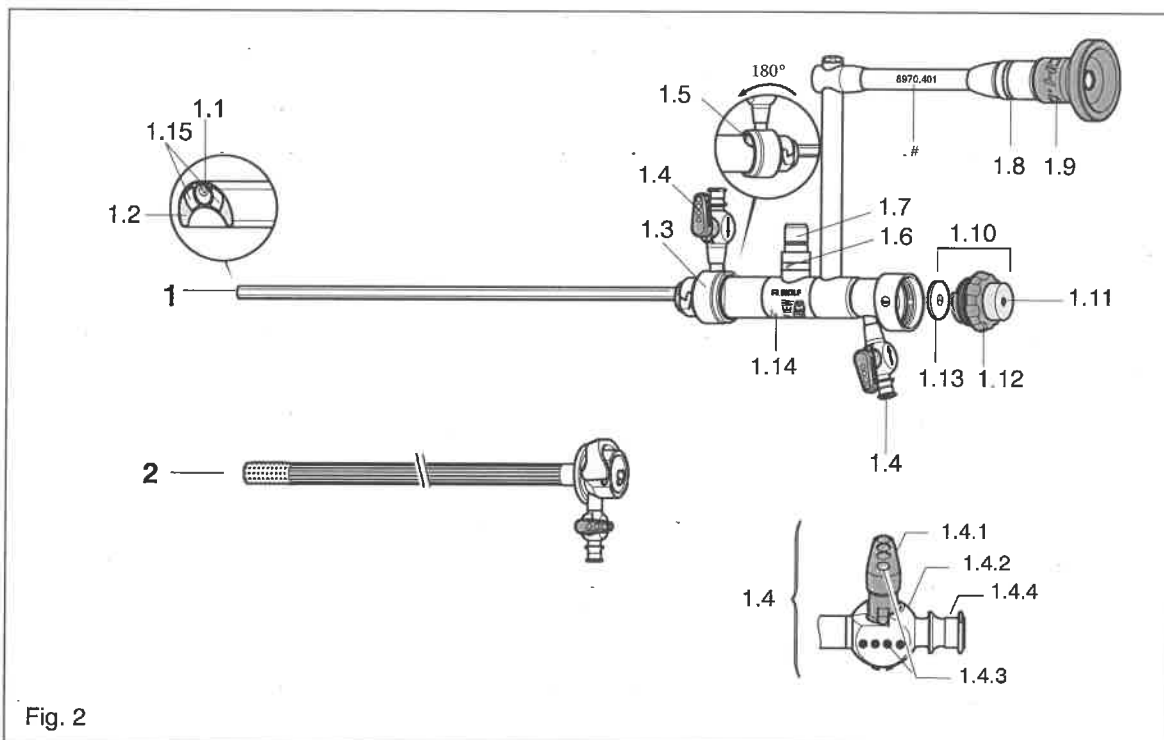


Fig. 2

5.1 Legend and Identification

Item	Designation	Item	Designation
1	"Piranha Scope" PANOVIEW Operating Telescope	1.5	Locking button
1.1	Objective lens	1.6	Code number for fiber bundle diameter
1.2	Light exit	1.7	Cold-light connector
1.3	Irrigation adapter	1.8	Colored ring, orange indicating direction of view 12°
1.4	Stopcock, disassemblable	1.9	Eyepiece
1.4.1	Stopcock plug	1.10	Sealing element, assembly, consisting of:
1.4.2	Stopcock housing	1.11	Sealing cap
1.4.3	Identification of passage on: -stopcock plug -stopcock housing	1.12	Sealing element
1.4.4	Luer fitting	1.13	Membrane valve
		1.14	Indication of direction of view
		1.15	Irrigation channel
2	Outer sheath for legend and identification see manual GA-D 345 / BB-D 345		
		#	Product no.

5.2 Symbols

Symbols	Designation
	Caution, consult ACCOMPANYING DOCUMENTS!
REF	Order no.
SN	Serial no.
	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 class IIa and above as well as sterile products or products with measuring function of class I are additionally identified with the code no. of the notified body (0124).

6 Use



CAUTION!

The products have only limited strength!

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.

Make sure that no missing parts remain in the patient.

Do not use the products if they are damaged or incomplete or have loose parts.

6.1 Preparation

- ◇ Perform a visual check (Sections 7 and 7.1)
- ◇ Unscrew the sealing element (1.12) and check that a membrane valve (1.13) is installed (fig. 3).
- ◇ Screw the sealing element (1.12) back on tightly (fig. 3).
- ◇ Install the sealing cap (1.11) (fig. 3).

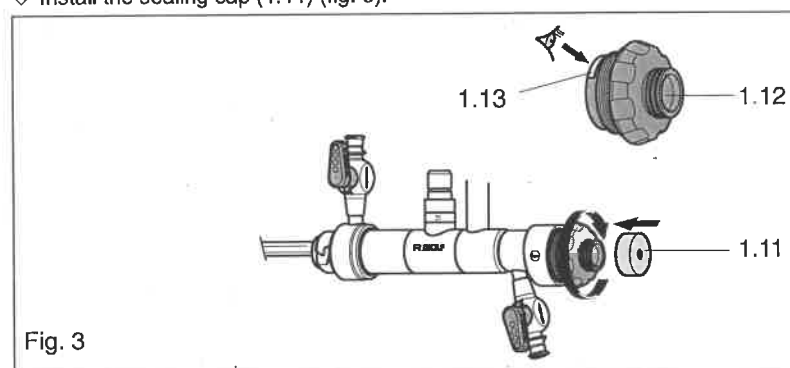


Fig. 3

6.1.1 Installing the irrigation adapter



NOTE!

When installing the irrigation adapter (1.3), it is necessary to overcome the resistance of the O-rings (x) (see section 8.1.1) making sure that the irrigation adapter (1.3) is properly aligned.

- ◇ Push on the irrigation adapter (1.3) as indicated by the arrow as far as it will go.

◆ The irrigation adapter (1.3) snaps into place.

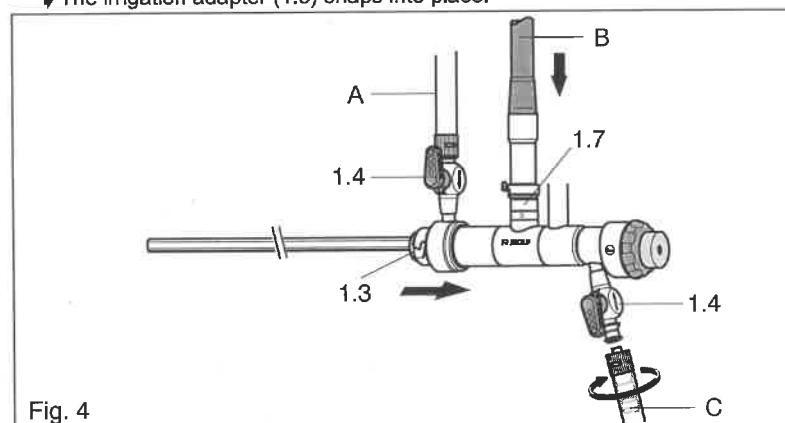


Fig. 4

- ◇ Connect the irrigation tube (A) to the irrigation stopcock (1.4).
- ◇ Connect flexible light cable (B) to the cold-light connector (1.7).
- ◇ If necessary, connect the irrigation tube (C) to the irrigation stopcock (1.4). (see section 6.2.1)

6.1.2 Insert the PANOVIEW Operating Telescope (1) into the outer sheath (2) of the resectoscope double-sheath system.

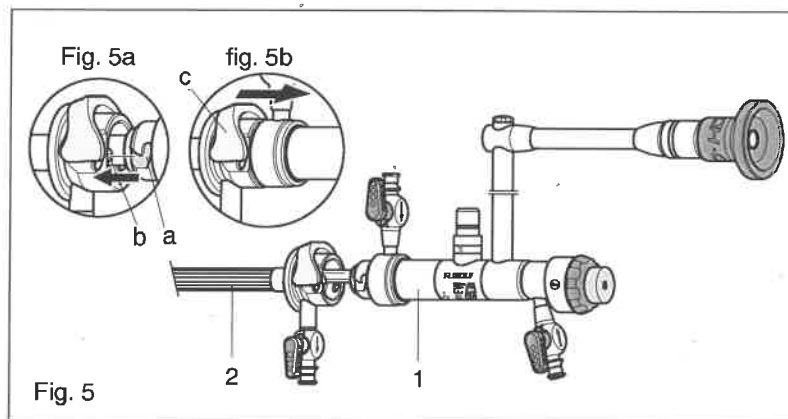
(Fig. 5)

◇ Locking (fig. 5a):

Insert the PANOVIEW Operating Telescope (1) into the outer sheath (2) in such a way that the recesses (a) and the pins (b) are aligned. Push together until the locking mechanism engages automatically.

◇ Unlocking (fig. 5b):

Push the saddle (c) of the outer sheath as indicated by the arrow and remove the PANOVIEW Operating Telescope (1).



◇ Carry out a function check (see section 7.2).

6.2 Additional notes and instructions for use

6.2.1 Morcellating



IMPORTANT!

Follow the morcellator manual!



IMPORTANT!

To prevent the bladder from collapsing, we recommend closing the drain stopcock (1.4) of the PANOVIEW Operating Telescope (1) during morcellation or using the drain stopcock as an additional supply stopcock to connect a second irrigation bottle. Evacuation is effected via the morcellator.

6.2.2 Nephroscopy

In conjunction with an "Amplatz sheath" (26 Fr.) the PANOVIEW Operating Telescope (1) can also be used as a nephroscope.

For nephroscopy, puncture the hollow organ with a conventional puncture set and dilate to the required width (if not carried out before).

Push the "Amplatz sheath" forward into the hollow system of the kidney via the dilator.

Remove the dilator and insert the PANOVIEW Operating Telescope (1) instead. Carry out this procedure under X-ray control.

6.2.3 Current



WARNING!

Danger of electric shock!

Patient leakage currents can add up if the endoscope is combined or used jointly with powered products or endoscopic accessories.

Check the combination.

6.2.4 Light



NOTE!

To achieve optimum light transmission, the fiber bundle diameters of the endoscope and fiber light cable must be the same.

Possible consequences when using a fiber light cable with

- ♦ excessive diameter:
excessive heating at the coupling point with the endoscope
- ♦ insufficient diameter:
reduced light output

For the suitable fiber bundle diameter please refer to the product number of the fiber light cable.

- ♦ The identification (1.6) on the cold-light connector (1.7) must correspond with the 2 numbers to the right of the dot in the type number. (Fig. 6)

Exception: Fiber light cable 8061.933 has a fiber bundle diameter of 3.5 mm.

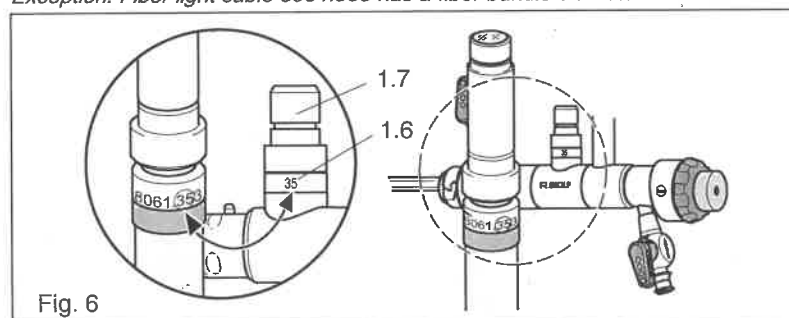


Fig. 6



CAUTION!

Intense heat due to high light energy!

Under unfavorable conditions, the use of the high-temperature-resistant flexible light cable 8063.353 can cause increased temperatures at the coupling point between the flexible light cable and the endoscope.

Danger of burns for the user and risk of damage to the endoscope!

Reduce the light output, use flexible light cable product no. 8061.xxx / 8062.xxx instead if required.



IMPORTANT!

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



WARNING!

Intense 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 extreme heat at the light exit area causes high temperatures or even ignition if the endoscope is placed onto heat-sensitive flammable surfaces (dark drapes, etc.).

Store the endoscope in a safe place.

Switch off the light source if you do not use the endoscope for a prolonged period of time.

6.2.5 Irrigation fluid



CAUTION!

Liquid may be absorbed into the patient's body as a result of overpressure!

This will cause severe injury to the patient.

To ensure a low-pressure continuous irrigation effect, the drain stopcock (1.4) should be open while supplying irrigation fluid.

6.2.6 Laser application



CAUTION!

Do not work outside the scope's field of view!

Inadvertent tissue damage as well as damage to the distal end of the endoscope and instrument parts are possible.

Activate the laser only after the tip of the laser fiber has become fully visible through the endoscope and contact is made with the planned application area.



CAUTION!

High temperatures due to highly coherent laser beam!

The heat generated by the laser beam reduces the strength of instrument parts.

Do not direct the laser beam at instrument parts, in particular not at plastic parts.

Keep a safe distance.



CAUTION!

Do not work without a filter!

Danger of eye injuries!

Use the endoscope only with a suitable filter on the eyepiece.

6.2.7 Bladder syringe, evacuator

The bladder syringe or evacuator can only be used in conjunction with the resectoscope continuous irrigation double-sheath system consisting of outer and inner sheath.



IMPORTANT!

In addition, follow the manual "Syringes, evacuator", order no.: GA-D 096.

7 Checks



CAUTION!

*Be careful if products are damaged or incomplete!
Injuries of the patient, user or third parties are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged or incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.*

7.1 Visual check

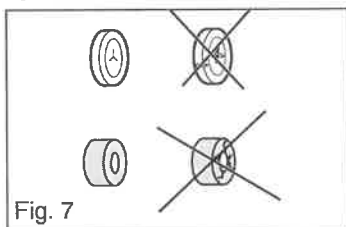


Fig. 7

7.2 Function check

- ◇ Check instruments and accessories for damage, sharp edges, loose or missing parts and rough surfaces.
 - Check the membrane valve (1.13), sealing cap (1.11) and O-rings (x) (not shown) for proper condition and replace if necessary (fig. 7).
- ◇ Any lettering, labeling or identification necessary for the safe intended use must be legible.
 - Missing or illegible lettering, labeling or identification leading to wrong handling and reprocessing must be reinstated.

- ◇ Check the suction and irrigation flow prior to each use.
- ◇ Check that the PANOVUE Operating Telescope (1) can be rotated in the outer sheath (2) of the resectoscope.

Check image quality and light output:

- ◇ Deposits on the glass surfaces can cause a spotted or blurred field of view and thus impair light transmission considerably.
 - Clean the glass surfaces with a swab soaked with alcohol (wooden swab carrier, not metal or plastic) remove hard-to-remove deposits with instrument cleaner* (fig. 8).

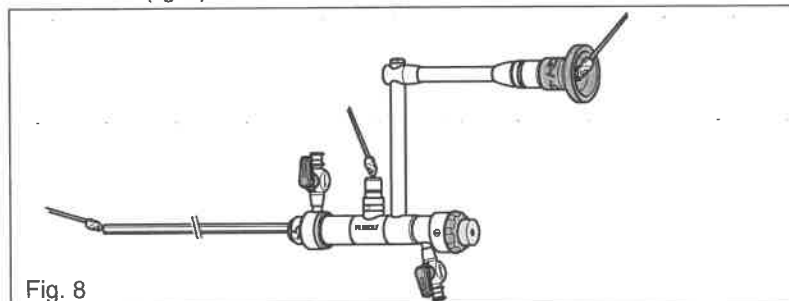


Fig. 8

*for this see also the "Notes and instructions on the reprocessing of Richard Wolf products, accessories and devices", order no.: GA-J 020.

- ◇ Hold the distal end of the endoscope towards a light source.
 - Broken fibers will appear as black dots at the cold-light connector (1.7). If approx. 30% of the fibers are broken, the light output is no longer sufficient (fig. 9).

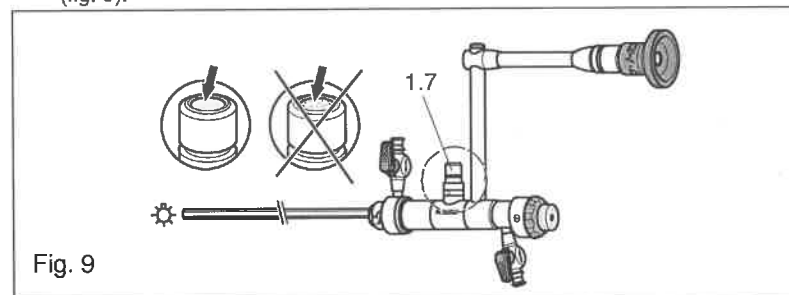
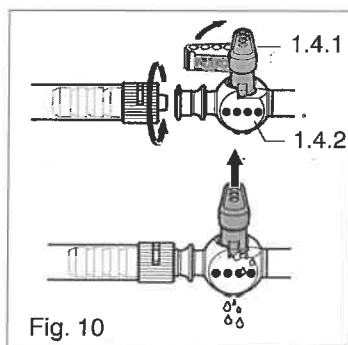


Fig. 9

7.2.1 Disassemblable stopcock



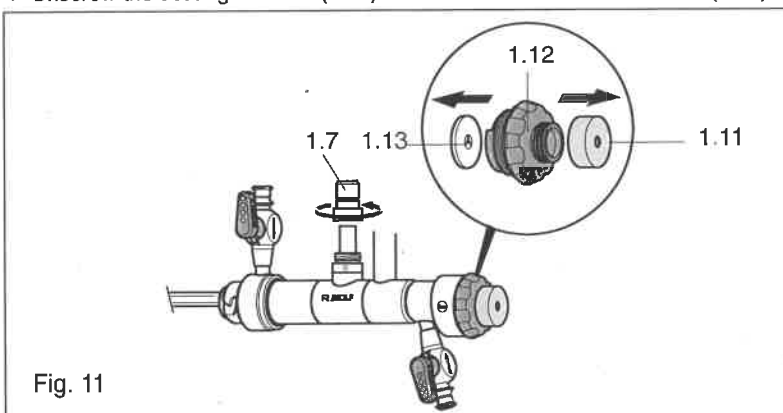
- ◇ Check that the stopcock plug (1.4.1) has positively engaged in the stopcock housing (1.4.2).
- ◇ Check the stopcocks (1.4) for leak-tightness.
 - ▶ Turn the stopcock plug (1.4.1) to the closed position.
 - ▶ In case of leaking stopcocks: Replace stopcock plug (1.4.1).
- ◇ Check that the stopcock plug (1.4.1) moves easily in the stopcock housing (1.4.2).

8 Reprocessing and maintenance

8.1 Disassembly before cleaning

8.1.1 Disassembly of PANOVIEW Operating Telescope (1)

- ◇ Unscrew the cold-light connector (1.7).
- ◇ Remove the sealing cap (1.11).
- ◇ Unscrew the sealing element (1.12) and remove the membrane valve (1.13).

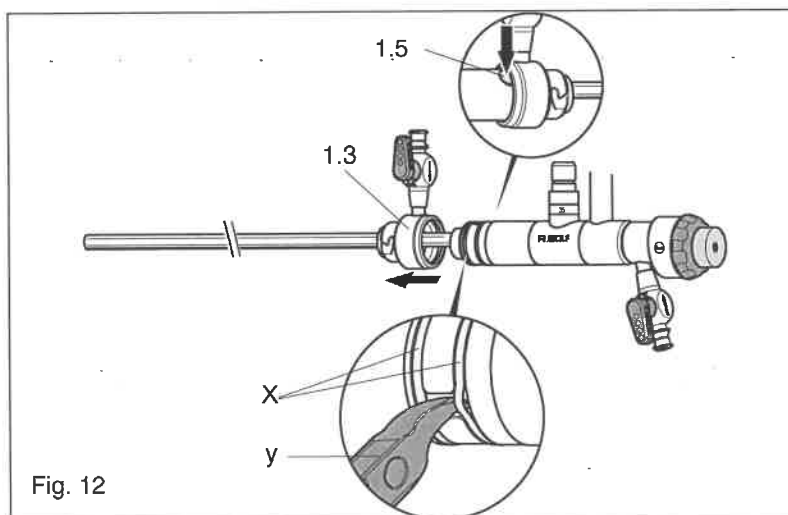


IMPORTANT!

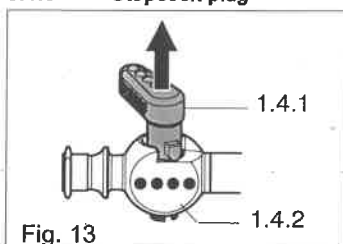
Replace the membrane valve (1.13) after each use.

8.1.2 Disassembly of irrigation adapter (1.3)

- ◇ Push the locking knob (1.5) and remove the irrigation adapter (1.3) as indicated by the arrow (fig. 12).
 - ◇ Remove O-rings (x) (order no.: 9500118, PU = 10/pkg.) with O-ring tool (y) (order no. 15 106.230).
- For this, use the recess, as shown in figure 10, not to damage the O-rings (x).

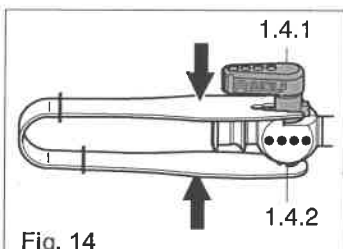


8.1.3 Stopcock plug



Without disassembly tool (fig. 13)

- ◇ Pull the stopcock plug (1.4.1) out of the housing.
- The stopcock plug (1.4.1) disengages from the stopcock housing (1.4.2).



With disassembly tool (fig. 14)

- ◇ Push forward the disassembly tool as far as it will go, as shown in figure 14, and compress.
- The stopcock plug (1.4.1) disengages from the stopcock housing (1.4.2).
- ◇ Remove the stopcock plug (1.4.1).

8.2 Manual reprocessing

- ◇ Wet preparation at the point of use
- ◇ Disassembly before cleaning: see section 8.1
- ◇ Manual cleaning with an approved enzymatic cleaner.

8.3 Machine reprocessing

- ◇ Dry preparation at the point of use
- ◇ Disassembly before cleaning: see section 8.1
- ◇ Machine cleaning with an approved enzymatic cleaner.

8.3.1 Machine reprocessing in the reprocessing basket



IMPORTANT!

Before machine reprocessing, manually pre-clean the irrigation adapter (1.3). Before placing the PANOVIEW Operating Telescope (1) into the reprocessing basket, attach irrigation adapter (1.3).

- ◇ Screw on the supplied rinsing adapter (A).
- Manually pre-clean the contact surfaces of the PANOVIEW Operating Telescope (1) before.
- ◇ Place the stopcock plugs (1.4.1), sealing element (1.12), sealing cap (1.11) and new membrane valves (1.13) into the utensils basket.
- ◇ Place the cold-light connector (1.7) onto the corresponding holder.
- ◇ Connect the rinsing hoses through the meshes, establish all connections.



IMPORTANT!

For machine cleaning, do not place the sheath (2) into the reprocessing basket, place into the corresponding holders in the rinsing basket instead.

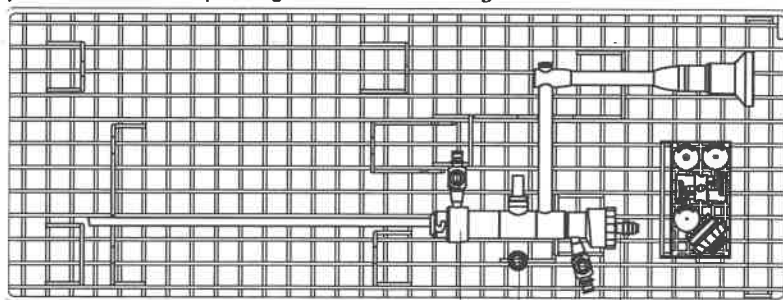


Fig. 15

1.3 1.7 A

8.4 Checks

- ◇ Carry out a visual check: see section 7.1

8.5 Assembly before sterilization



NOTE I

Before sterilization screw on the threaded connections only loosely

◆ *to allow a sufficient flow of the sterilization medium.*

◆ *to avoid stress cracks in plastic parts.*

Tighten all screw connections before use.

8.5.1 Stopcock plug (1.4.1)

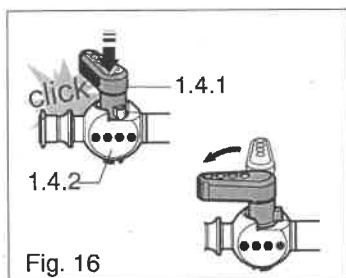


Fig. 16

- ◇ Insert the stopcock plug (1.4.1) into the stopcock housing (1.4.2).
- ◆ The stopcock plug (1.4.1) engages noticeably.
- ◇ Open the stopcock plug (1.4.1).

8.5.2 Assembly of PANOVIEW Operating Telescope (1)

- ◇ Disconnect the rinsing adapter (A) and place into the small parts basket.
- ◇ Screw on the cold-light connector (1.7) (fig. 17).

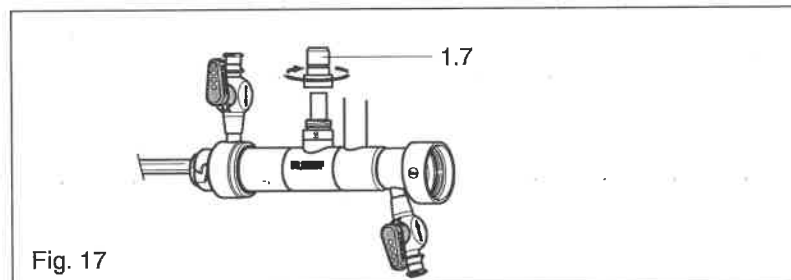


Fig. 17

- ◇ Install a new membrane valve (1.13) in the sealing element (1.12) (fig. 18).

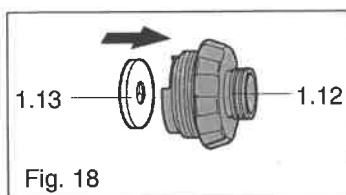


Fig. 18

- ◇ Screw on the sealing element (1.12) with the membrane valve (1.13) in place, then unscrew at least 1 turn. Tighten firmly before use. (Fig. 19)

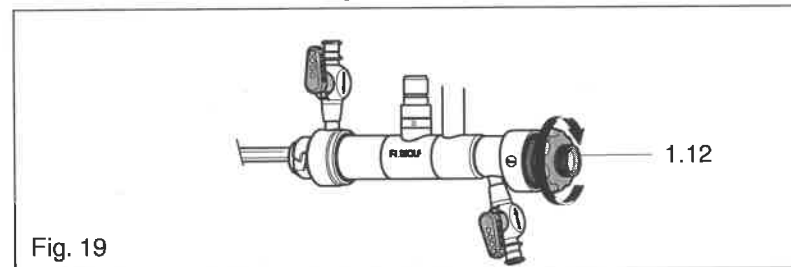


Fig. 19

8.6 Sterilization

8.6.1 Sterilization in the reprocessing basket

- ◇ Assemble the PANOVIEW Operating Telescope (1) as previously described under section 8.5.

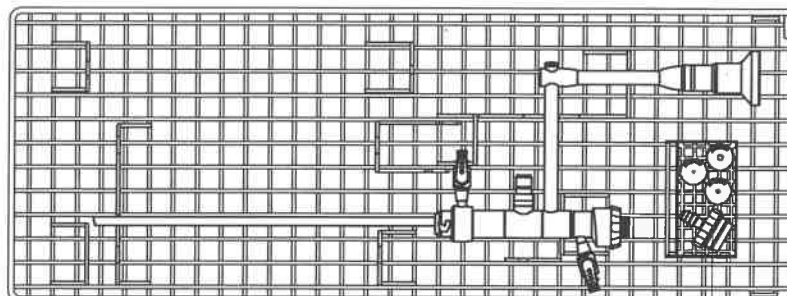


Fig. 20

A

- ◇ For sterilization pack the reprocessing basket in a special packaging in accordance with the country-specific standards, e. g. EN 868, or a corresponding sterilization container.

8.6.2 Steam sterilization

- ◇ Steam sterilization at 132° C (270° F) using a Pre-Vac cycle at an exposure time of 4 minutes with a 20 minute dry time.

8.6.3 Gas sterilization

- ◇ Gas sterilization using ethylene oxide (EtO).

9 Technical data and order data

For additional information on reprocessing, see Manual GA-J020 "Reprocessing of RICHARD WOLF Heat Stable Instruments".

Product no.	Designation, technical data		
8970402	"Piranha Scope" PANOVIEW Operating Telescope: passage 15 Fr. (5 mm); direction of view 12°; working length = 199 mm; image angle 80°		
8920.311		Sealing part, complete for instruments up to 5.5 mm dia.	
Product no.	Color coding	Designation, technical data	
8655.374	yellow	Continuous irrigation outer sheath; outside dia. Ø 26 Fr.	Resectoscope continuous irrigation double-sheath system
8655.384		Continuous irrigation inner sheath; outside dia. Ø 24 Fr.	
8654.17		Obturator	
8415.12		Viewing obturator	
8655.334	green	Continuous irrigation outer sheath; outside dia. Ø 24.5 Fr.	Resectoscope continuous irrigation double-sheath system
8655.344		Continuous irrigation inner sheath; outside dia. Ø 22.5 Fr.	
8654.16		Obturator	
8415.11		Viewing obturator	

10 Spare parts and accessories

Illustration	Product no.	Designation
	8061.353	Light cable
	89.103	Membrane valve (yellow) PU = 10 / pkg.
	15 176.106	Sealing element
	89.00	Sealing cap, black - for instruments up to 2.4 mm
	89.01	Sealing cap, red-orange - for instruments over 2.4 mm up to 3.4 mm
	89.02	Sealing cap, blue - for instruments over 3.4 mm up to 5.1 mm
	15461.039	Irrigation adapter
	886.00	Luer lock tube fitting
-	889.01	Tube connector
-	889.02	Connection tube
	8095.00	Cold-light connector
	15 106.230	O-ring tool
	9500118	Spare O-rings (yellow), PU = 10 / pkg.
	896.0003	Spare plug, 4.2 mm passage identification: 4 pegs packaging unit = 5 / pkg.
	38310.0001	Disassembly tool
	38 042.211	Reprocessing basket
	64 164.031	Rinsing adapter for machine reprocessing in the reprocessing basket
	WO51	Instrument oil
	103.00	Rubber bulb
	6.01	Cleaning brush diameter 11 mm, brush length 100 mm, total length 360 mm

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, brochures or contact Richard Wolf or your 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 Reprocessing basket

Operating conditions	Sterilize in accordance with the endoscopes and endoscopic accessories placed into the reprocessing baskets
Storage conditions	Store in accordance with the endoscopes and endoscopic accessories placed in the reprocessing baskets
Transport conditions, empty	-20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa



IMPORTANT!

Do not use the reprocessing basket for shipping the endoscopes or endoscopic accessories.

11.2 Disposal of product, packaging material and accessories

For the disposal observe the laws and regulations valid in your country.

♦ For further information please contact the manufacturer.

12 **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.