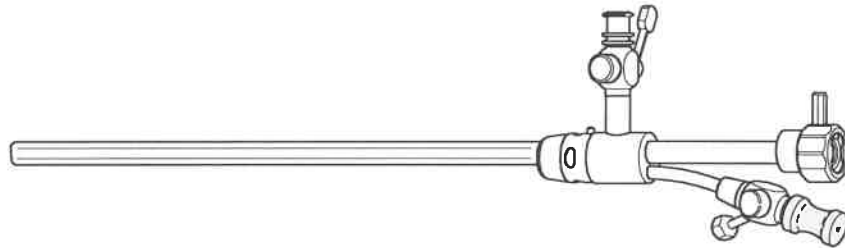


Instructions



Working Insert
for Continuous Irrigation

8654.911

⚠ Important general instructions for use ⚠

Ensure that this product is used only as intended and described in this instruction manual, by adequately trained and qualified personnel, and that maintenance and repair is only carried out by authorized specialized technicians.

Use this product only with the combinations and with the accessories and spare parts listed in this instruction manual. Use other combinations, accessories and replacement parts only if they are expressly intended for this use and if the performance and safety requirements are met.

Reprocess the products before every application and before returning them for repair 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 - USA only:

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

Safety instructions and levels of danger

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

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1 Technical description

The continuous-irrigation working insert consists of:

- ◇ Sheath tube
- ◇ Locking cone
- ◇ Irrigation stopcock
- ◇ Insertion stopcock for auxiliary instruments
- ◇ Locking mechanism for endoscope

2 Intended use

The continuous-irrigation working insert is used for guiding flexible auxiliary instruments up to max. 7.5 Fr.

Continuous irrigation is established via the irrigation stopcock through the continuous-irrigation working insert and the drain through the E-line resectoscope sheath.

3 Indications and field of use

For diagnosis and therapy of the lower urogenital tract in conjunction with endoscopic accessories. This product may only be used by adequately qualified and trained medical personnel.

4 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.

5 Combinations

- ◇ E-line resectoscope sheaths from 24 Fr.
- ◇ Endoscope, 4mm, direction of view 12°, 25° or 30°
- ◇ Probes up to 7.5 Fr.



CAUTION !

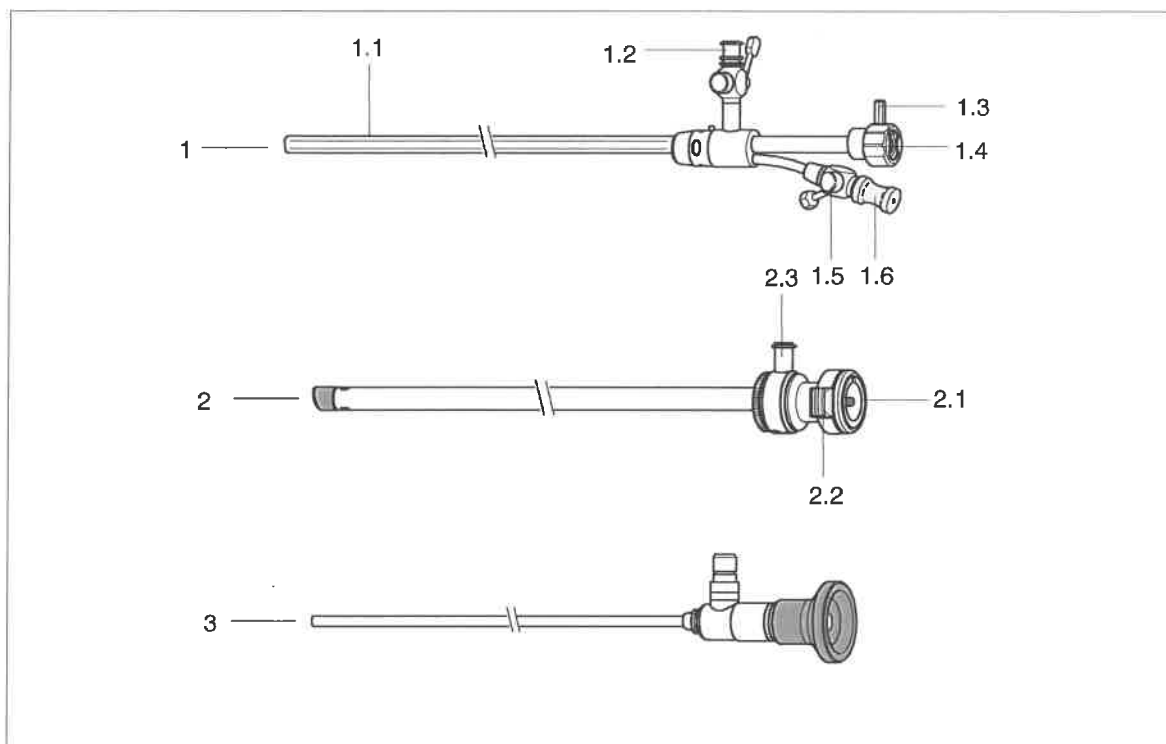
Be careful if products are incorrectly combined !

Injury may result to the patient, user or others, and damage may result 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.

6 Illustration



6.1 Legend and Identification

Item	Designation	Item	Designation
1	Continuous-irrigation working insert	2	E-line resectoscope sheath
1.1	Sheath tube	2.1	Locking mechanism
1.2	Irrigation stopcock	2.2	Tab
1.3	Locking lever	2.3	Luer connector (drain connector)
1.4	Locking mechanism		
1.5	Insertion stopcock	3	Endoscope

Symbols	Meaning
	Attention, consult ACCOMPANYING DOCUMENTS
REF	Order number
	Lot identification number
SN	Series number
CE	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).

7 Use



CAUTION!

The products only have 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.

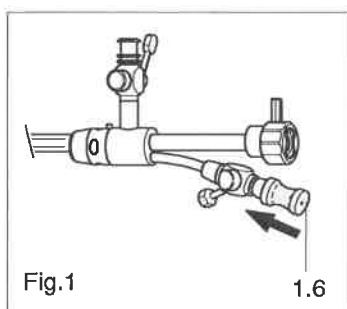
Do not use products which are damaged, incomplete or have loose parts.

7.1 Preparation



NOTE !

For the preparation of the E-line resectoscope sheath used in combination with this product, please refer to the latest instruction manual on E-line resectoscope sheaths.



◇ Installing the rubber cap (1.6) (Fig. 1).

◇ Carry out a visual check: see sections 7 and 7.1

7.1.1 Inserting the endoscope into the working insert

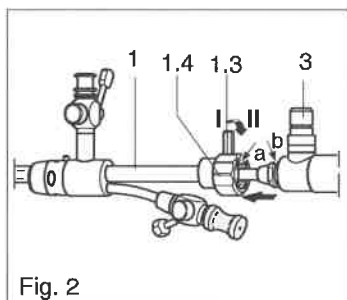


CAUTION!

With probes/auxiliary instruments that are bigger than 6 Fr., first insert the probe/the auxiliary instrument into the inner sheath and then insert the endoscope (3).

In reverse order, the probe/the auxiliary instrument may be jammed and damaged or destroyed.

Figure 2:



◇ The locking lever (1.3) is in position I.

To lock:

◇ Insert the endoscope (3) axially into the working insert (1).

‣ The pin (a) engages in the groove (b).

◇ Turn the locking lever (1.3) to position II.

‣ The two components are locked together.

To unlock:

◇ Turn the locking lever (1.3) to position I.

‣ The locking mechanism (1.4) is unlocked.

◇ Remove the endoscope (3).

7.2 Notes and instructions for the use of laser probes

Example using "Sidefire" laser probes:

The transurethral laser irradiation of the prostate by means of "Sidefire" laser probes can be considered an alternative for TURP (Transurethral Resectoscopy of the Prostate), subject to a corresponding indication.

For optimum view of the laser probe and the operating area, 4 mm telescopes 12°, 25° or 30° are recommended.

If the prostate is inflamed, a combination of laser application and traditional TURP is recommended.

Figure 3:

- ◇ Insert the working insert (1) with the endoscope (3) and the laser probe (x) into the E-line resectoscope sheath (2) already in situ.

To lock:

- ◇ Push together until the locking mechanism (2.1) engages automatically.
 - ◆ For this purpose, the pin (c) and the groove (d) must be aligned.

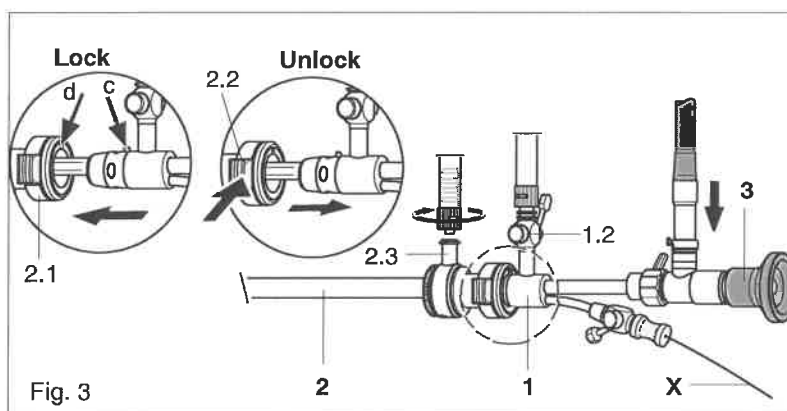


NOTE !

If the locking mechanism (2.1) won't click into place, push the tab (2.2) as far as it will go, then repeat the procedure.

To unlock:

- ◇ Push the tab (2.2) and remove the working insert (1).



- ◇ Connect the irrigation tube to the irrigation stopcock (1.2) and the other end of the tube to the irrigation device.
- ◇ Connect the drain tube to the drain stopcock on the Luer connector (2.3), and the other end of the tube to a suction pump, the siphon effect, however, may be sufficient.
- ◇ Connect the recommended flexible light cable to the endoscope and the other end of the cable to a light source.
- ◇ Connect the laser probe (x).



CAUTION!

The operating time may be extended and the comfort for the user reduced due to a wrong size of the laser probe or the auxiliary instrument or by a blockage in the insertion channel.

Use only laser probes or auxiliary instruments up to 7.5 Fr.

Before use, check that the laser probe/the auxiliary instrument can be inserted easily and without any resistance.

Do not use instruments that are difficult to insert because they may be damaged during insertion.

7.2.1 Laser application

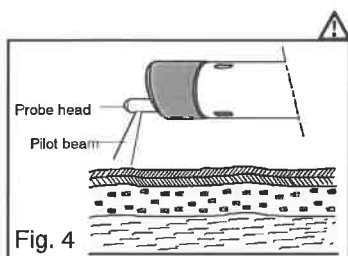
For laser application, follow the notes and instructions of the laser device manufacturer as well as the general regulations on the use of lasers. Wear the mandatory personal protection gear.



CAUTION !

Danger of injury if probe head is lost!

If used incorrectly, the distal probe head can come off and remain in the patient. Recover lost probe head immediately using a flexible grasping forceps (max. 7 Fr.) or an optical forceps.



CAUTION !

Do not damage edge of sheath!

Do not work outside the field of view!

Activate the laser only after the tip of the laser fiber has become fully visible through the scope and the area to be treated is visible. Follow the probe manufacturer's instructions!

When using sheaths with windows or distally oblique sheath, rotate "Side-fire" laser probe only within a range between 4- and 8 o'clock. Otherwise there is the risk of destroying instruments parts, in particular in applications near the edge of the sheath (at distances of less than 10mm) (Fig. 4). Check exit of pilot beam!



CAUTION !

High temperatures due to highly coherent laser beam on metal or plastic parts!

The heat generated by the laser beam reduces the strength of instrument parts and can also cause thermal damage or injuries due to sharp edges.

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

Keep a safe distance between the exit of the laser beam and instrument parts (such as the edges of the sheath)!



CAUTION !

Danger of eye injury when using lasers without filter attachment!

Use a suitable filter attachment on the endoscope eyepiece.

8 Checks



CAUTION!

Be careful if products are damaged or incomplete!

Injury may result to the patient, user or others.

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 any loose parts for repair.

Do not attempt to do any repairs yourself.

8.1 Visual check

- ◇ Check instrument parts and accessories for
 - damage
 - sharp edges
 - loose or missing parts
 - rough surfaces.
- ◇ 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.

8.2 Functional check

- ◇ Check the irrigation and suction function in conjunction with the resectoscope sheath used.
- ◇ Check the individual instruments for easy assembly and easy operation of the locking mechanism. Replace instruments if the locking mechanism
 - ◆ won't provide a secure connection
 - ◆ cannot be locked or is difficult to lock.

9 Reprocessing and maintenance



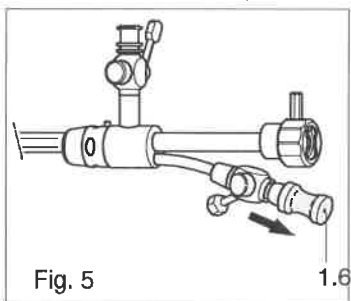
IMPORTANT!

Follow the current **"Notes and instructions on the reprocessing of Richard Wolf products, accessories and devices"**, order no.: GA-J 020.

Do not use disinfectants containing peracetic acid without corrosion protection agents, phenols or chlorine components for the reprocessing of Richard Wolf products.

Do not exceed the maximum exposure time specified by the manufacturer of the disinfectants used.

9.1 Disassembly before cleaning



- ◇ Remove the rubber cap (1.6).

9.2 Manual reprocessing

- ◇ Wet preparation at the point of use
- ◇ Disassembly before cleaning: see section 9.1
- ◇ Manual cleaning / disinfection

9.3 Machine reprocessing

- ◇ Dry preparation at the point of use
- ◇ Disassembly before cleaning: see section 9.1
- ◇ Machine cleaning / disinfection

9.4 Checks

- ◇ Perform a visual check (see section 8.1)

9.5 Sterilization

9.5.1 Steam sterilization

- ◇ Steam sterilization at 134°C (272°F) using the fractional pre-vacuum method.

9.5.2 Steris™ and Sterrad™ sterilization procedures



NOTE!

The Steris™ and Sterrad™ sterilization procedures have been approved for use on our endoscopes and endoscopic accessories only with regard to material compatibility. For information about possible limitations, such as discoloration of plastic materials, as well as further notes see the latest version of **"Notes and instructions on the reprocessing of Richard Wolf products, accessories and devices"**, order no. GA-J 020.

Efficacy has been certified by the sterilizer manufacturers in microbiological tests. Follow the manufacturer's instructions.

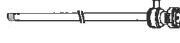


NOTE!

Steris™ sterilization procedure:

Connect all channels to the system to ensure thorough reprocessing of all hollow spaces by the reprocessing medium. Follow the manufacturer's instructions.

10 Technical data and order data

Illustration	Product no.	Designation, Technical data
	8654.911	Working insert with continuous-irrigation, WL = 222 mm
	8654.xxx	E-line resectoscope sheath from 24 Fr.
	8654.3xx	E-line rotatable resectoscope sheath from 24 Fr.
	8654.xxx	Telescopes 4 mm, direction of view 12°, 25° or 30°

11 Spare parts and accessories

Illustration	Product no.	Designation, Technical data
	886.00	Luer lock tube connector
	88.01	Rubber cap "RIWO" red-orange
	6.03	Cleaning brush

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.

12 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.

12.1 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.

