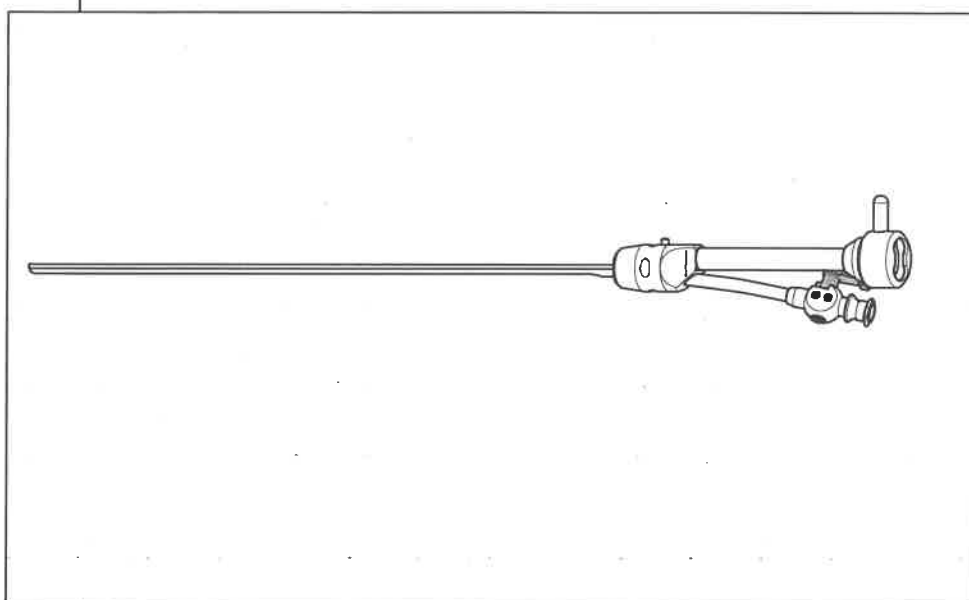


Instruction Manual



Working insert
8632.284

⚠ Important general notes and instructions ⚠

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 not impaired. Do not alter the product in any way.

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 and others.

This manual is an integral part of the product and must be stored in such a way that it is accessible at any time during its entire life cycle. This manual must be passed on to any subsequent owner.

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

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 Technical description

Working insert consisting of:

- ◇ Guide tube
- ◇ Locking cone
- ◇ Locking mechanism
 - ◆ for fixing the endoscope in place
- ◇ Instrument port stopcock
 - ◆ for inserting auxiliary instruments

2 Intended use

The working insert is used for guiding flexible/semi-rigid auxiliary instruments.

This product is exclusively intended for use by specialized medical personnel and must only be used by medically qualified and adequately trained persons.

3 Indications and field of use

Diagnostics and therapy in urology (urogenital tract) as well as gynecology (genital tract/hysteroscopy). The product must 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 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.

5 Combinations

The working insert is used in conjunction with endoscopes, continuous-irrigation resectoscopes (24.5 Fr. / 26 Fr.) or urethro-cystoscope sheaths (21 Fr.) and continuous-irrigation cystoscope sheaths (22.5 Fr., 24.5 Fr.), as well endoscopic accessories (flexible and semi-rigid auxiliary instruments such as laser fibers). (see section 10 "Spare parts and accessories").



NOTE !

Due to the gas bubbles generated during a laser application, we recommend using continuous-irrigation resectoscopes with a beveled sheath window.



CAUTION !

Do not combine products incorrectly!

Injuries of the patient, user or others as well as damage to the product is possible.

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

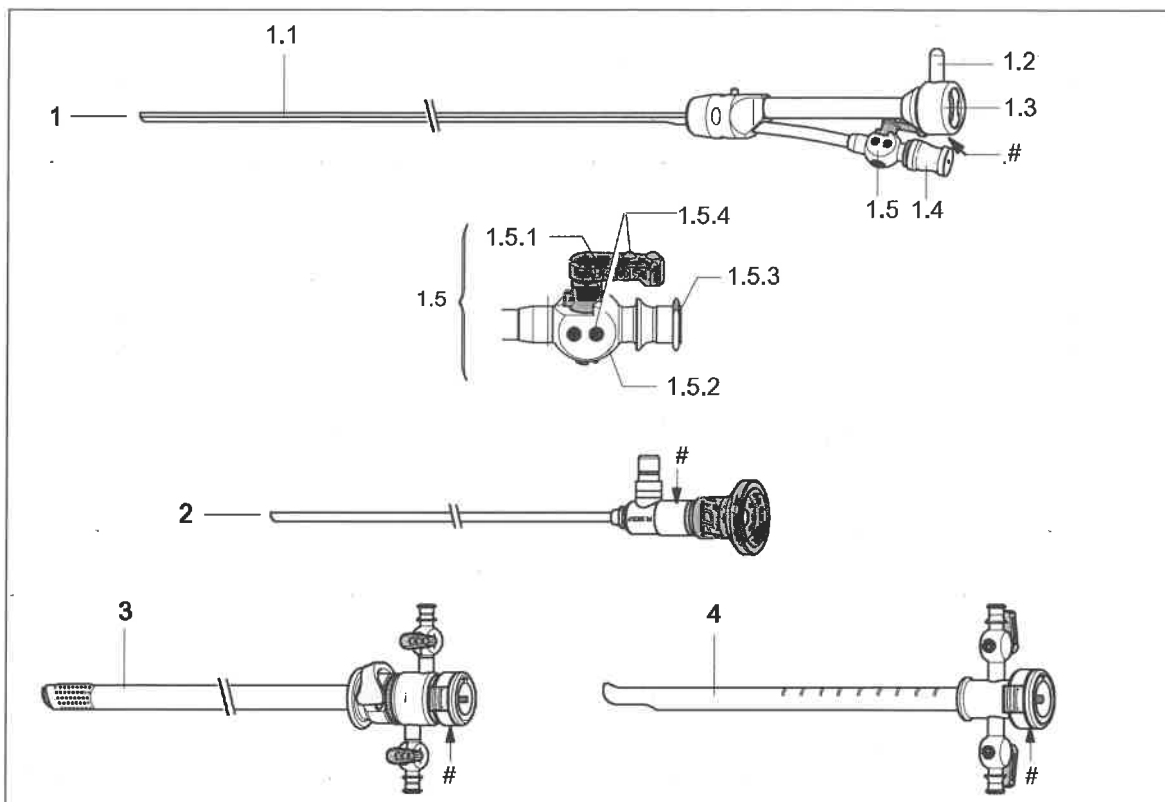
Follow the instruction manual of the products used in combination with this product.

◆ Instruction manual for endoscopes: GA-S 001

◆ Instruction manual for continuous-irrigation resectoscopes:
GA-D 345 / GA-D 342

◆ Instruction manual for urethro-cystoscopes: GA-D 321

6 Illustration



6.1 Legend and identification

Item	Designation	Item	Designation
1	Working insert	1.1	Guide tube
		1.2	Locking lever
2	Endoscope	1.3	Locking mechanism
		1.4	Rubber cap
3	Resectoscope continuous irrigation sheath	1.5	Insertion port stopcock, with removable plug
		1.5.1	Stopcock plug
4	Urethro-cystoscope sheath	1.5.2	Stopcock housing
		1.5.3	Passage identification on -stopcock plug -stopcock housing
#	Product no.	1.5.4	Luer fitting

6.2 Symbols

Symbols	Designation
	Caution, consult ACCOMPANYING DOCUMENTS !
REF	Order no.
SN	Serial no.
CE	Identification in conformity with EEC directive 93/42/EEC on medical products, is only valid if the product and/or its packaging is provided with this identification. 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 no. of the notified body (0124).

7 Application



CAUTION !

The products have only limited strength !

Applying excessive force will cause damage (e.g. a bending of the endoscope), impairs the function and therefore endangers the patient.

Ensure sufficient relaxation of the patient during the intervention !

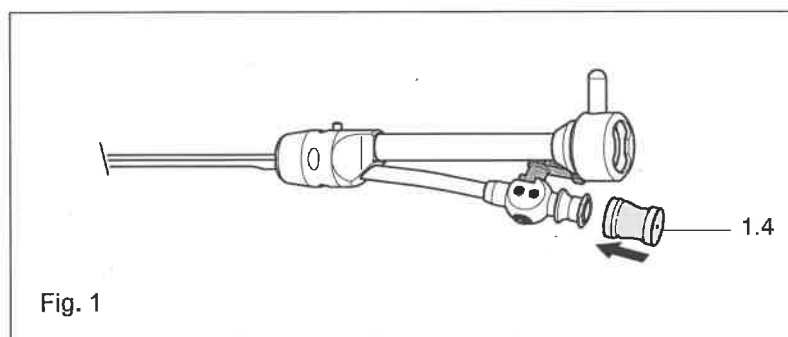
Immediately before and after each use, check the products for damage, loose parts and completeness.

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.

7.1 Preparation

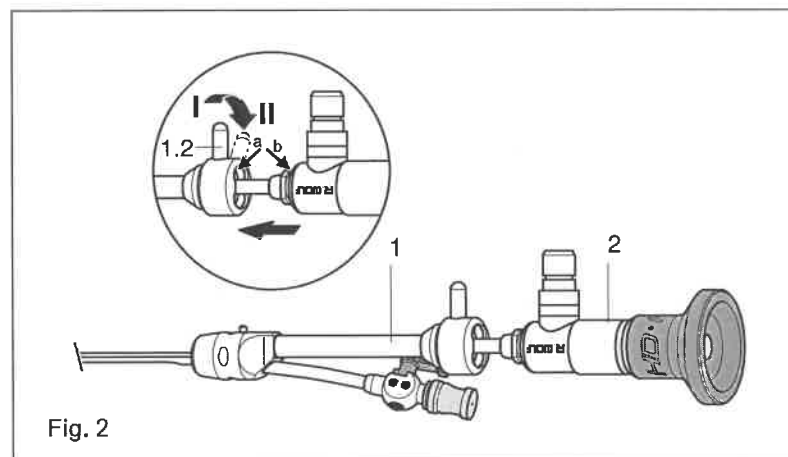
- ◇ Install the rubber cap (1.4) (Fig. 1).



- ◇ Perform a visual check (Sections 7 and 7.1)

7.1.1 Inserting the endoscope

- ◇ Turn locking lever (1.2) to position "I".
- ◇ Insert the endoscope (2) into the working insert (1).
 - ◆ The nose (a) engages in the groove (b).
- ◇ Turn the locking lever (1.2) to position "II".
 - ◆ The two components are locked together.



7.1.2 Inserting the working insert into the sheath

Locking:

- ◇ Insert the working insert (1) into the sheath (3) in such a way that the groove (c) and the pin (d) are aligned and push together until the connection engages automatically (Fig. 3)



NOTE!

If the connection won't engage automatically, push the tab (X) as far as it will go and repeat the procedure.

Unlocking:

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

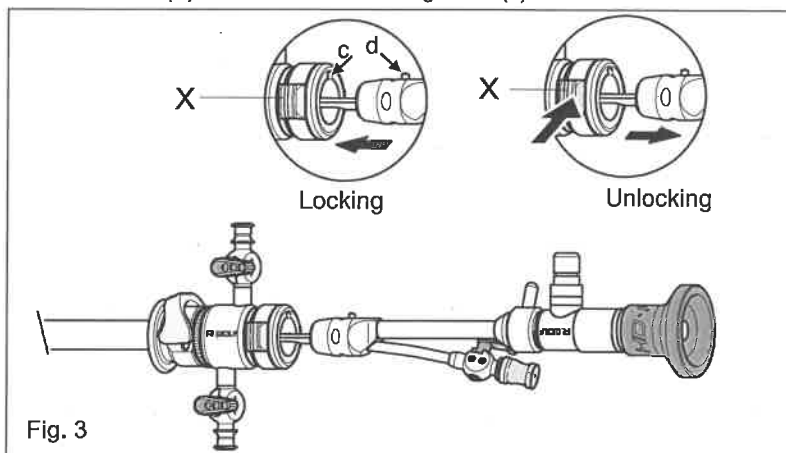


Fig. 3

- ◇ Connect the irrigation tube to the luer fitting on the supply stopcock and the other end to the irrigator.
- ◇ Connect the drain tube with luer fitting to the drain stopcock.
- ◇ Connect a suitable light cable, and connect the latter to a suitable light projector.

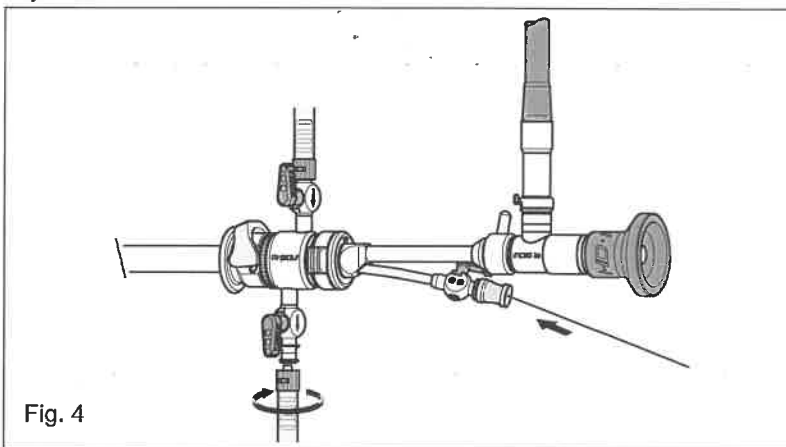


Fig. 4

- ◇ Insert an auxiliary instrument (e.g. laser fiber).



CAUTION!

A wrong size of the auxiliary instrument or a blockage in the insertion channel will extend the operating time and reduce user comfort.

Before use, make sure that the auxiliary instrument can be inserted easily and without resistance.

Do not use auxiliary instruments that are difficult to introduce because they can become damaged during insertion.

Insert only auxiliary instruments up to max. 6.5 Fr..

7.2 Additional notes and instructions for use

7.2.1 Inserting a laser fiber

The laser fiber is guided in the working channel, but it is axially and radially freely movable because the working insert does not have a holder or stop to align GreenLight™ laser fibers.



CAUTION !

Laser probe can rotate through 360° !

Be careful in particular in the case of:

cysto-urethroscope sheaths with sheath window and resectoscope sheaths with a nib or beveled distal end.

When rotating and activating the laser probe within the distal sheath end (nib, window, beveled end) the edges of the sheath and endoscope can be damaged.

Activate the laser only after the tip of the laser probe has become fully visible through the scope and contact is made with the intended area to be treated.

Follow the notes and instruction on the use of lasers in section 7.2.2 !

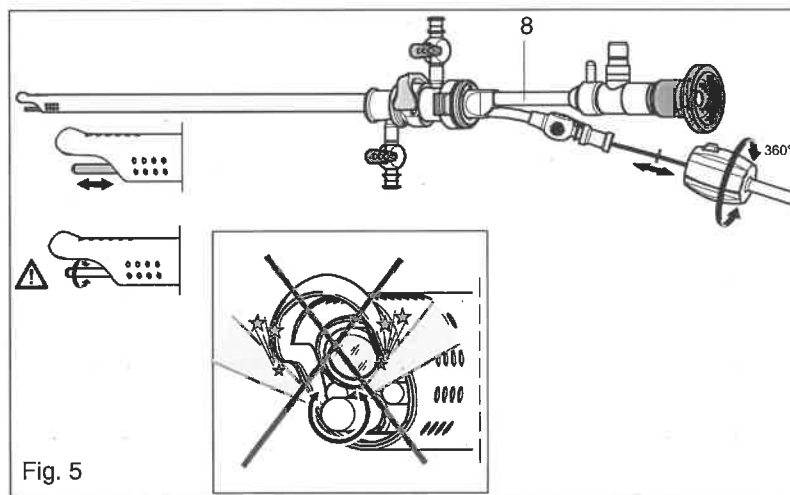


Fig. 5

7.2.2 Laser application

When applying a laser make sure you follow the laser device manufacturer's instructions as well as the general regulations on the use of lasers.

Wear the required personal protection equipment.

CAUTION !

Do not work outside of 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 is fully visible in the scope's field of view and after having reached the application site.

The laser fiber must project at least 10 mm from the sheath. (Fig. 6)

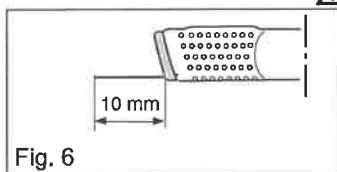


Fig. 6



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 and ceramic components.

Keep a safe distance.



CAUTION !

There is a risk of eye injuries when working without filter attachment !

Use a suitable filter attachment on the eyepiece of the scope.

7.2.3 Current



WARNING !

Leakage currents !

Patient leakage currents can add up if endoscopes are combined with powered endoscopic accessories or other electrically operated products are connected to the instrument set.

Danger of electric shock !

Before use check the combination for leakage currents.

8 Checks



CAUTION !

Be careful if products are damaged or incomplete !

Injuries of the patient, user or others are possible.

Run through the checks before and after each use.

Do not use the products if they are damaged, 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 and accessories for damage, sharp edges, loose or missing parts and rough surfaces.
- ◇ Before every use, check the ceramic insulation on the distal end of the sheath.
 - ◆ Do not use the instruments if they are damaged (cracks, fractures)!
- ◇ Check the rubber cap (1.4) for damage and replace if necessary.
- ◇ Any lettering, labeling or identification necessary for the safe intended use must be legible.
 - ◆ Missing or illegible inscriptions and labels that can lead to wrong handling and reprocessing must be reinstated.

8.2 Function check

- ◇ Check the individual instrument for easy assembly and proper functioning of the locking mechanism(s).
 - ◆ Replace the instruments if the connection although locked is not secure.
 - ◆ Replace the instruments if the connection cannot be locked or is difficult to lock.
- ◇ Check the instrument channels / ports for patency (free passage).

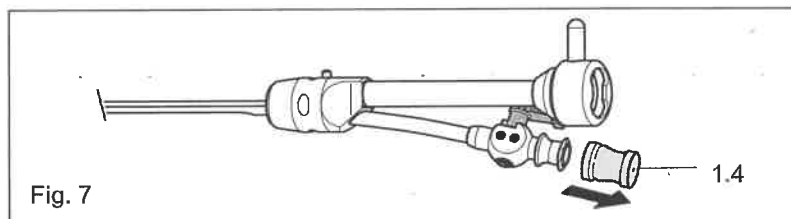
Stopcock with removable plug (1.5):

- ◇ Check that the stopcock plug (1.5.1) has positively engaged in the stopcock housing (1.5.2).
- ◇ Check for leak-tightness.
- ◇ Check that the stopcock plug (1.5.1) moves easily in the stopcock housing (1.5.2).

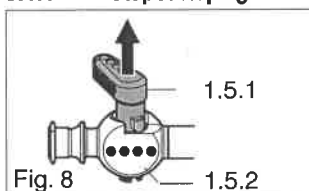
9 Reprocessing and maintenance

9.1 Disassembly before cleaning

- ◇ Remove rubber cap (1.4).

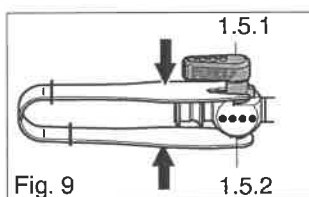


9.1.1 Stopcock plug



Without disassembly tool (fig. 8)

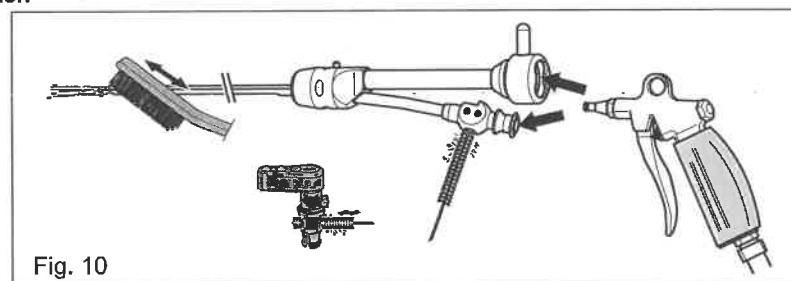
- ◇ Remove the stopcock plug (1.5.1).
 - ◆ The stopcock plug (1.5.1) disengages from the stopcock housing (1.5.2).



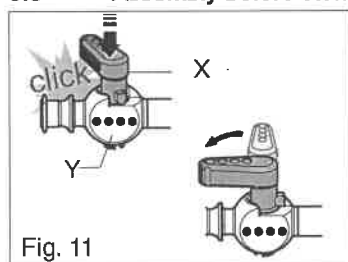
With disassembly tool (fig. 9)

- ◇ Slide the disassembly tool forward as far as it will go, then compress as shown in the figure.
 - ◆ The stopcock plug (1.5.1) disengages from the stopcock housing (1.5.2).
- ◇ Remove the stopcock plug (1.5.1).

9.2 Manual cleaning illustration



9.3 Assembly before sterilization



Stopcock plug (fig. 11)

- ◇ Insert the stopcock plug (1.5.1) into the stopcock housing (1.5.2).
 - ◆ The stopcock plug (1.5.1) engages noticeably.
- ◇ Open the stopcock plug (1.5.1).

9.4 Reprocessing procedure

The following table describes the validated reprocessing procedure for the working insert.



IMPORTANT!

Due to the product design and the materials used it is not possible to define a specific limit of the maximum permissible reprocessing cycles. The service life of medical products is defined by their function and gentle handling.

Before defective products are returned for repair, they must have gone through the entire reprocessing cycle.

The user is obliged to make sure that the reprocessing process including the resources, material and personnel is suited to reach the required reprocessing results.

The state of the art and national laws require that validated processes be followed.

Reprocessing guide:		
Preparation at the point of use:	Directly after use, remove any coarse soiling from the instruments and rinse out hollow spaces with a 5 ml syringe filled with water. Do not use any fixing or setting agents or hot water (>40°C) as this will bake the residues to the surfaces and may have a negative impact on cleaning. May use an approved pre-treat spray prior to transport	
Transport:	Safe storage, transport and shipment of the instruments to the reprocessing room in a closed container to prevent damage to the instruments and contamination of the environment.	
Precleaning:	Disassemble the working insert before cleaning : see sections 9.1 and 9.1.1 Rinse out the working insert for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a cleaning gun.	
Cleaning:	Manual cleaning See figure 10 1. Immerse the working insert in an enzymatic cleaning solution for at least 5 minutes. ♦ Fill the working channel with this solution before immersion. 2. Brush with a soft brush at least 5 times to remove any residues. 3. Rinse out the working channel with a 5 ml syringe filled with enzymatic cleaning solution. 4. Then rinse out the working channel for 20 seconds or, in pulsed mode, with 5 pressure surges (3 - 4 bar) using a cleaning gun.	Machine cleaning Manually preclean the working insert before machine cleaning. (see figure 10) Place stopcock plug (1.5.1) and rubber cap (1.4) into the small-parts basket. Connect the stopcock housing (1.5.2) via the luer connector (1.5.4) to the washer-disinfector. Vario-TD program (without disinfection cycle) ♦ 4 min of pre-cleaning with cold water ♦ Empty ♦ 6 min of washing with cleaning agent at 55°C ♦ Empty ♦ 3 min of neutralization ^{*)} (>40°C) ♦ Empty ♦ 2 min of intermediate rinsing with warm tap water (>40°C) ♦ Empty ^{*)} depending on the quality of the neutralization solution, add an acid based on citric acid.
Disinfection:	1. Dry instruments to avoid diluting the disinfectant solution. 2. Immerse the working insert only in an approved disinfectant solution following the manufacturer's recommendations for the immersion time. ♦ Fill the working channel with this solution before immersion. 3. Then rinse out the working insert thoroughly for at least 15 seconds with processed water using a cleaning gun or as recommended by the disinfectant manufacturer.	Carry out thermal machine disinfection following the national requirements regarding the A0 value (see DIN EN ISO 15883).
Drying:	Manual drying: Dry the outside of the working insert using a sterile lint-free disposable cloth or swab, dry the hollow spaces with filtered compressed air.	Drying of instruments using the washer-disinfector drying cycle. If necessary, additional manual drying can be achieved using a sterile lint-free disposable cloth or swab. Dry hollow spaces with filtered compressed air.
Function check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the instrument appears visually clean. Carry out a visual check: see section 8.1	
Packaging	Wrap or package the instruments as required by the standard.	
Assembly before sterilization	See section 9.2 Do not attach the rubber cap (1.4) for sterilization. Place it in the tray with the accessory items.	

Sterilization:	Sterilize using the fractional pre-vacuum method (ISO13060/ISO17665) following the corresponding national requirements. ◆ Temperature exposure time: 4 min at 134°C +4°C (273°F +7°F) 132°C +4°C (270°F +7°F) ◆ Drying time: 20 - 30 min ◆ Maximum sterilization temperature: 138°C.
Storage	Store the sterilized instruments in a restricted area at approximately 24°C / 75°F with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%; per ANSI/AAMI ST79.
Validation:	The following test instructions, materials and machines were used during validation: ◆ Machine cleaning agent: alkaline cleaning agent 0.5% neodisher FA (Dr. Weigert) ◆ Manual cleaning agent: enzymatic cleaning agent 0.5% neodisher MediClean (Dr. Weigert) ◆ Manual disinfectant: Cidex (Advanced Sterilization Products) ◆ Automatic washer-disinfector: G 7735 CD Miele ◆ Washer-disinfector rack: MIC rack cart
Additional instructions:	The user is obliged to validate his process in accordance with DIN EN ISO 17664.

9.5 Low-temperature sterilization

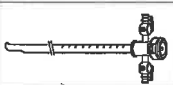
For possible alternate sterilization methods, refer to our website www.richardwolfusa.com under "Reprocessing & Sterilization" for listings of the Richard Wolf instruments that have been approved for various reprocessing methods.

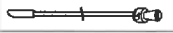
10 Technical data and order data

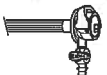
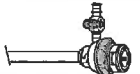
Illustration	Product no.	Designation
	8632.284	Working insert, passage 6.5 Fr.; WL = 218.5 mm

11 Spare parts and accessories

Illustration	Product no.	Designation, Technical data
	8654.422	PANOVIEW telescope; 4 mm direction of view 30°, working length = 307 mm;

Laser cystoscope 21 Fr.		
	8652.0441	Urethro-cystoscope sheath passage 1 x 10 Fr. or 2 x 6 Fr.

Laser cystoscope	22.5 Fr.	24.5 Fr.	
	8632.026	8632028	Continuous-irrigation outer sheath
	8632.027	8632029	Continuous-irrigation inner sheath
	8632.126	8632128	Obturator
	-	8632728	Viewing obturator

Laser resectoscope 24.5 Fr.		
	8655.334	Continuous-irrigation outer sheath
	8655.344	Continuous irrigation inner sheath
	8654.16	Obturator
	8415.11	Viewing obturator

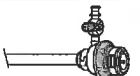
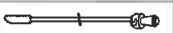
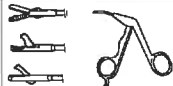
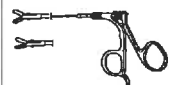
Laser resectoscope 26 Fr.		
	8655.374	Continuous-irrigation outer sheath
	8655.384	Continuous-irrigation inner sheath
	8654.16	Obturator
	8415.11	Viewing obturator

Illustration	Product no.	Designation, Technical data
	8992.63	Biopsy and grasping forceps, working length 335 mm; diameter 2.2 mm.
	8992.64	Rigid hook scissors, working length 335 mm; diameter 2.2 mm.
	8992.68	Rigid biopsy forceps, working length 335 mm; diameter 2.2 mm.
	8642.60	Biopsy forceps, rigid 5 Fr., working length 355 mm
	8642.65	Grasping forceps, rigid 5 Fr., working length 355 mm
	6199.00	Water jet cleaning pistol, includes 8 different attachments and wall-mountable rack
	6.01	Cleaning brush Total length TL = 360 mm; brush dia. $\varnothing$ = 11 mm; brush length BL = 100 mm
	88.01	Rubber cap, red-orange (item 1.4) for instruments up to 7 Fr.
	88.005	Rubber cap, red-orange (item 1.4) for instruments up to 5 Fr.
	896.0001	Spare plug, 2.5 mm passage identification: 2 pegs packaging unit = 5 / pkg.
	38310.0001	Disassembly tool

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

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 comply with the country-specific laws and regulations.

♦ For further information please contact the manufacturer.

13 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.

