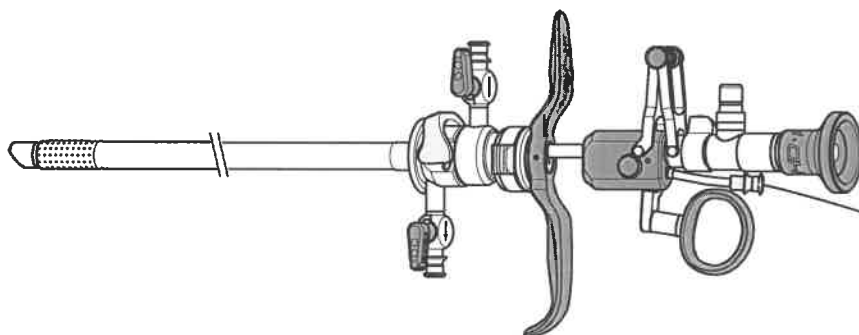


Instruction Manual



Working element and guide tube for laser fiber

8654.xxx

⚠ 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 element**
 - ◆ Passive: Laser fiber is reset by spring pressure. Open grip
 - ◆ with probe guide channel
 - ◆ with locking cone, lock body and thumb ring
 - ◆ with proximal locking mechanism
- ◇ **Guide tubes for laser fiber**
 - ◆ for guiding different laser fibers in parallel with the telescope
 - ◆ with distal loop for keeping the tissue away in the case of thin laser fibers
- ◇ **Option: Sterile universal sealing valve (single-use item)**

2 Intended use

The working element is used in conjunction with the corresponding instruments, in particular for guiding laser fibers during endoscopically controlled operations.

- ◇ **Working element**
 - ◆ houses and fixes the PANOVIEW telescope 12° / 30° and various guide tubes and allows controlled insertion of the laser fiber into the operating field under visual control.
 - ◆ allows the connection of the sterile universal sealing valve to the insertion port (with luer connector)
- ◇ **Guide tubes for laser fiber**
 - ◆ guides different laser fibers in parallel with the telescope
 - ◆ with distal loop for keeping the tissue away in the case of thin laser fibers
- ◇ **Option: Sterile universal sealing valve (disposable item)**
 - ◆ for insertion of auxiliary instruments from 1 - 6 Fr.

These products are exclusively intended for use by specialized medical personnel and must only be used by adequately instructed persons.

3 Indications and scope

For diagnosis and therapy via the transurethral passage in the lower urogenital tract, e.g. TURP (transurethral resection of the prostate) or via a percutaneous passage in the case of tumors in the renal pelvis or stenoses.

4 Contraindications and side effects

4.1 Contraindications

- CJD** - Creutzfeldt Jakob Disease or a
- vCJD** - Variant of the Creutzfeldt-Jakob Disease
- BSE** - Bovine Spongiform Encephalopathy; so-called mad cow disease (e.g. Creutzfeldt-Jakob Disease)
- TSE** - Transmissible Spongiform Encephalopathy

On the basis of the patient's general condition the doctor in charge must decide whether the planned use is possible or not.

Comply with the laws and regulations valid in your country.

For further notes and instructions please refer to the latest medical literature.

Contraindications directly related to the product are presently unknown.

4.2 Side effects

No side effects are to be expected if the system is used as intended.

5 Combinations

The working element and the guide tubes for laser fibers are used in conjunction with:

- ◇ Endoscopes
- ◇ Sheaths
- ◇ Light projectors and fiber light cables
- ◇ Pumps for irrigation and aspiration
- ◇ Cameras and couplers
- ◇ Laser fiber
- ◇ Lasers
- ◇ Endoscopic accessories



CAUTION!

Do not combine products incorrectly!

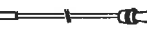
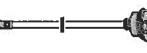
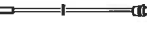
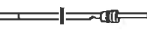
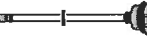
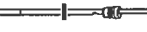
Injuries of the patient, user or others as well as damage to the product are possible.

The different products may only be combined if the intended use and the relevant technical data (working length, diameter, etc.) are the same.

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

5.1 Overview of permissible combinations

Item	Illustration	Product no.	Designation, Technical data
ENDOSCOPES for this, see GA-S001			
3		8654.431	PANOVIEW telescope 12° Overall length = 361.7 mm; Working length = 302.6 mm, Direction of view 12°; object field angle 60°; outside dia. Ø = 4.0 mm
		8654.422	PANOVIEW telescope 30° Overall length = 362.1 mm; Working length = 305 mm, Direction of view 30°; object field angle 60°; outside dia. Ø = 4.0 mm
"E-Line" CONTINUOUS-IRRIGATION DOUBLE-SHEATH SYSTEM for this, see GA-D345 and BB-D345			Color coding
4		8655314	Continuous-irrigation outer sheath 24.5 Fr.
5		8655324	Continuous-irrigation inner sheath 22 Fr.
6		865415	Obturator 22 Fr. for the afore mentioned continuous-irrigation inner sheath
4		8655.334	Continuous-irrigation outer sheath 24.5 Fr.
5		8655.344	Continuous-irrigation inner sheath, complete
6		8654.16	Obturator 22 Fr. for the afore mentioned continuous-irrigation inner sheath, complete
-		8415.11	Viewing obturator 22 Fr. for the afore mentioned continuous-irrigation inner sheath, complete
			green

Item	Illustration	Product no.	Designation, Technical data	
-		8655.374	Continuous-irrigation outer sheath 26 Fr.	yellow
-		8655.384	Continuous-irrigation inner sheath, complete	
-		8654.17	Obturator 24 Fr. for the afore mentioned continuous-irrigation inner sheath, complete	
-		8415.12	Viewing obturator 24 Fr. for the afore mentioned continuous-irrigation inner sheath, complete	
-		8654.175	Dilation obturator 24 Fr. for the afore mentioned continuous-irrigation inner sheath, complete	
"Shark" RESECTOSCOPE CONTINUOUS-IRRIGATION DOUBLE-SHEATH SYSTEM for this, see GA-D366 and BB-D366				Color coding
-		8675424	Outer sheath 24 Fr.	green
-		8675322	Inner sheath 22 Fr.	
-		8673022	Obturator 22 Fr. for the afore mentioned inner sheath	
-		8673122	Viewing obturator 22 Fr. for the afore mentioned inner sheath	
-		8675426	Outer sheath 26 Fr.	yellow
-		8675324	Inner sheath 24 Fr.	
-		8673024	Obturator 24 Fr. for the afore mentioned inner sheath	
-		8673124	Viewing obturator 24 Fr. for the afore mentioned inner sheath	
-		8673224	Dilation obturator 24 Fr. for the afore mentioned inner sheath	
„E-Line" OPTICAL URETHROTOMES for this, see GA-D317				Color coding
-		8667.011	Sheath 20.5 Fr.	-
-		8667.111	Obturator centrally hollow, for the afore mentioned sheath	

6 Illustration

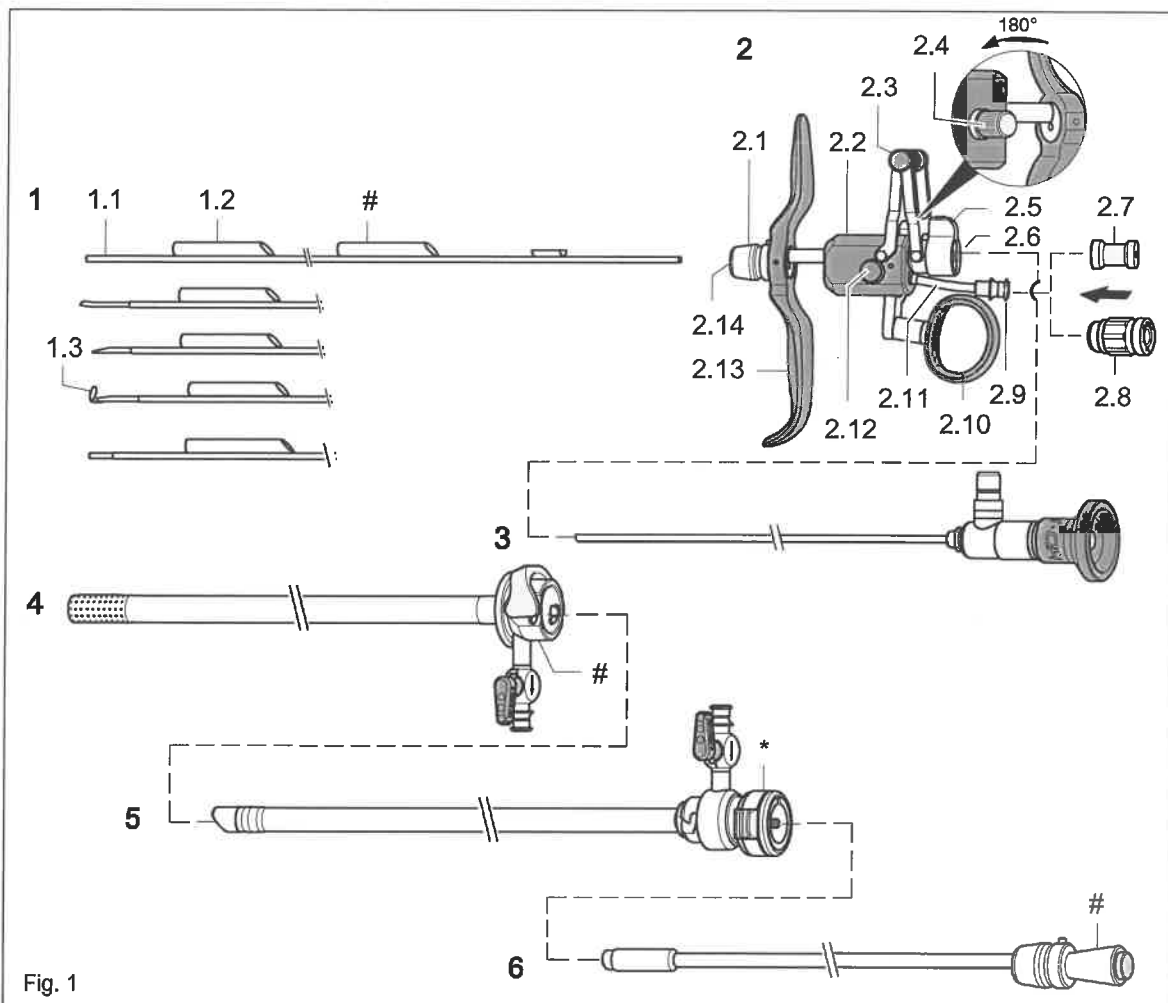


Fig. 1

6.1 Legend and Identification

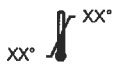
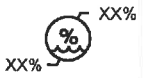
Item	Designation	Item	Designation
1	Guide tubes for laser fiber	2.9	Luer connector (insertion port)
1.1	Guide tube for laser fiber	2.10	Thumb ring
1.2	Telescope guide tube	2.11	Probe guide channel
1.3	Bracket	2.12	Pushbutton
2	Working element	2.13	Open grip
2.1	Locking cone	2.14	Holder
2.2	Lock body	3	PANOVIEW telescope 12° / 30°
2.3	Spring	4	Continuous-irrigation outer sheath, 24.5 Fr. / 26 Fr.
2.4	Lock screw	5	Continuous-irrigation outer sheath, 22 Fr. / 24 Fr.
2.5	Locking lever	6	Obturator
2.6	Clamping mechanism		
2.7	Rubber cap "RIWO"	*	Fr. specification
2.8	Sterile universal sealing valve (option)	#	Product no.

6.2 Symbols

6.2.1 Working element (2) and guide tubes (1)

Symbols	Designation
	Attention, Caution
	Follow the instruction manual
	Follow the manual
	Order number
	Lot designation
	Serial no.
	Manufacturer
	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).

6.2.2 Sterile universal sealing valve (2.8)

Symbols	Designation
	Follow the manual
	Order number
	Lot designation
	Manufacturing date
	Manufacturer
	Number, amount
	Expiration date
	Do not reuse
	Do not resterilize
	Sterilized with ethylene oxide
	Do not used if package is damaged
	Keep away from sunlight
	Temperature limitation
	Humidity limitation
	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 Use



WARNING!

Do not reprocess disposable items!

The service life of products marked as disposable, i.e. for one single use only, has been designed for only one use in or on a single patient.

If disposable items are reprocessed to be used again, this may impair/change the product properties and therefore endanger the patient, user and others.

Possible dangers / risk factors:

- ✦ *Strength problems*
- ✦ *Damage to the product*
- ✦ *Severe impairment of the function*
- ✦ *Substantially increased risk of infection*
- ✦ *Biocompatibility problems*

If a disposable item is reprocessed, the product responsibility lies with the user or reprocessor.

In this case, the manufacturer can no longer guarantee the safety and performance of the product.



CAUTION!

The products have only limited strength!

Excessive force will cause damage, impairs the function and therefore endangers 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.

7.1 Preparations

- ◇ Carry out a visual check: see sections 8 and 8.1

7.1.1 Working element (2):

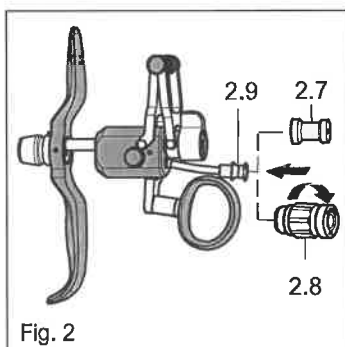


Fig. 2

- ◇ Place the rubber cap (2.7) onto the luer connector (2.9).
- ✦ Optionally, the sterile universal sealing valve (2.8) can be screwed onto the luer connector (2.9).

7.1.2 Inserting the PANOVIEW telescope (3) into the working element (2)

Fig. 3

Locking:

The locking lever (2.5) must be in position "I".

- ◇ Insert the PANOVIEW telescope (3) into the working element (2)
 - ◆ The pin (a) engages in groove (b).
- ◇ Turn locking lever (2.5) to position "II".
 - ◆ Both components are locked together.

To unlock:

The clamping lever (2.5) must be in position "II".

- ◇ Turn locking lever (2.5) to position "I".
 - ◆ The locking mechanism is unlocked.
- ◇ Remove the PANOVIEW operating telescope (3)

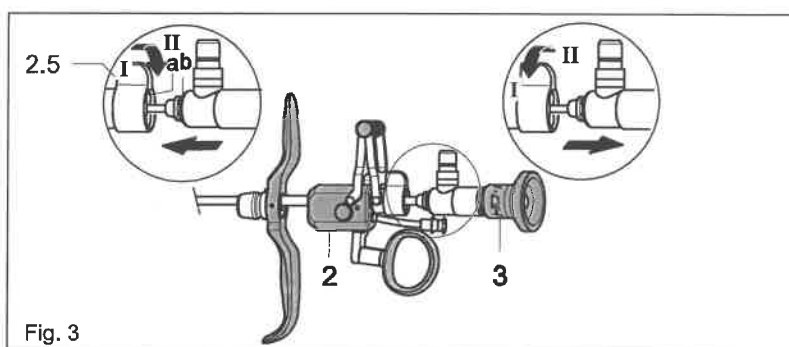


Fig. 3

7.1.3 Inserting the guide tube for laser fiber (1) into the working element (2).

Fig. 4

- ◇ Unscrew the setscrew (2.4) as far as it will go.
- ◇ Slide the telescope guide tube (1.2) over the PANOVIEW telescope (3).
- ◇ Engage the guide tube for laser fiber (1.1) into the receptacle (2.14) and insert into the lock body (2.2) as far as it will go.
- ◇ Tighten the setscrew (2.4) slightly, i.e. only hand-tight (Do not use force).
- ◇ Pull the distal end of the guide tube (1) to check that the connection is safe.

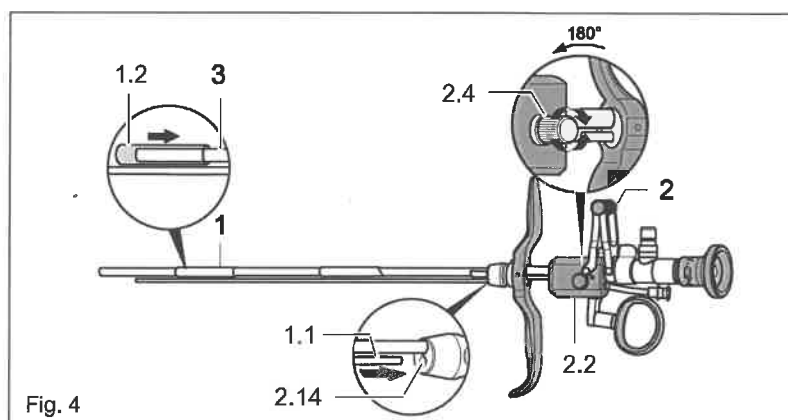


Fig. 4

7.1.4 Use with "E-Line" continuous irrigation double sheath system

Insert the continuous irrigation inner sheath (5) into the continuous irrigation outer sheath (4)

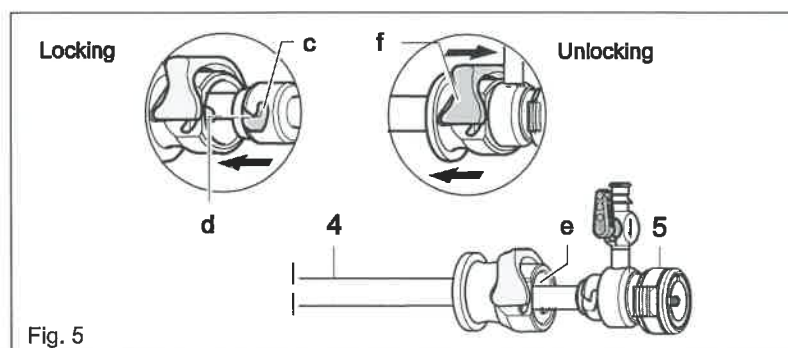
Fig. 5

Locking:

- ◇ Insert the continuous irrigation inner sheath (5) into the continuous irrigation outer sheath (4) in such a way that the recess (c) and the pins (d) are aligned. Push together until the locking mechanism (e) engages automatically.

To unlock:

- ◇ Push the loop (f) of the continuous irrigation outer sheath (4) in direction of arrow and remove the continuous irrigation inner sheath (5).



7.1.5 Use with "Shark" continuous irrigation double sheath system

Inserting the inner sheath(A) in the outer sheath (B)

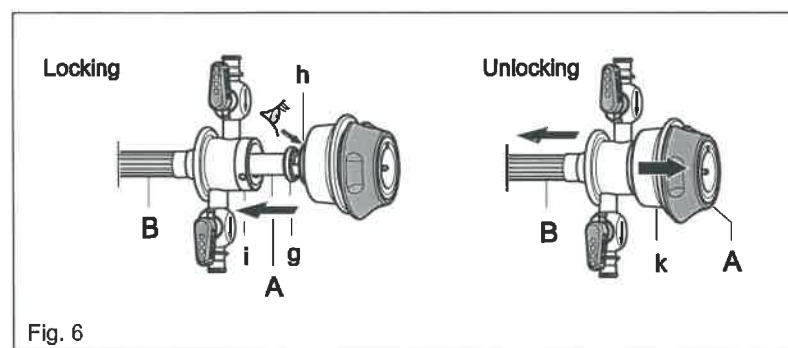
Fig. 6

Locking:

- ◇ Check that the o-rings (g) (h) on inner sheath (A) are in place.
- ◇ Insert the inner sheath (A) into the outer sheath (B) as far as it will go.
 - The outer sheath (B) engages (audibly) in the inner sheath (A) by means of automatic ball catch (i)
- ◇ Check for secure rotatable connection.

To unlock:

- ◇ Slide the outer ring (k) on the inner sheath (A) in direction of arrow as far as it will go, hold in this position and remove the outer sheath (B).



7.1.6 Inserting the working element (2) with guide tube for laser fiber (1) and PANOVUE telescope (3) into the resectoscope sheath



WARNING!

Danger of injury in the case of HF applications with continuous-irrigation inner sheath 8655324!

In its distal area the continuous-irrigation inner sheath 8655324 does not have a ceramic insulation.

Injuries to the patient, user or third parties are possible.

HF sparking and extreme heat can cause tissue damage as well as damage to the resectoscope and endoscope.

HF applications are not permissible.

Fig. 7

Locking:

- ◇ Insert the preassembled working element into the resectoscope sheath in such a way that groove (l) and pin (m) are aligned.
Push together until the locking mechanism / lock body (n) engages automatically.

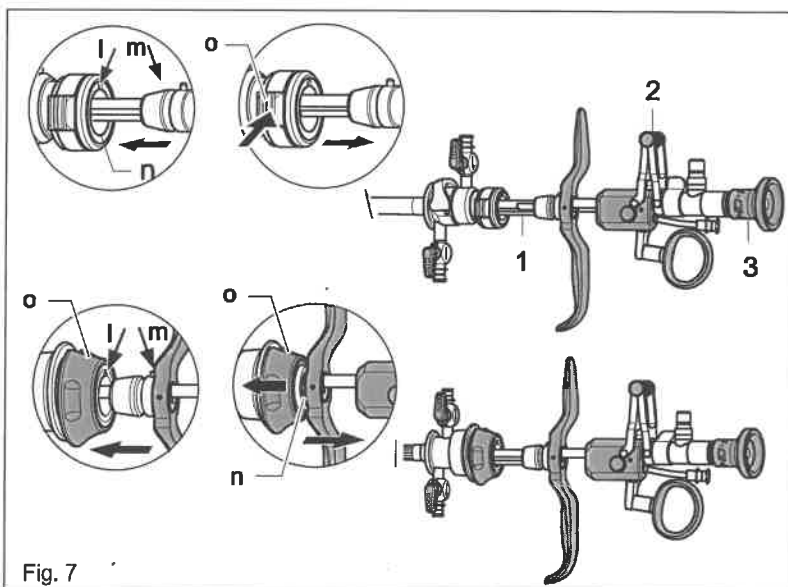


NOTE!

If the locking mechanism / lock body (n) won't engage, push the tab / actuation ring (o) as far as it will go, and repeat the procedure.

To unlock:

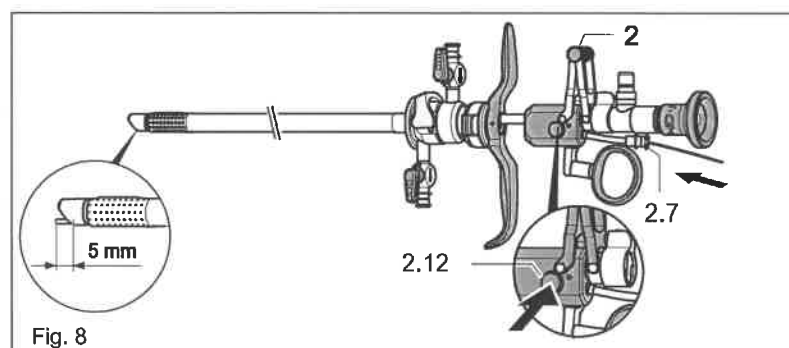
- ◇ Push the tab / actuation ring (o) in direction of arrow as far as it will go and remove the preassembled working element.



7.1.7 Inserting the laser fiber

Fig. 8

- ◇ Press and hold down the pushbutton (2.12)
- ◇ Insert the laser fiber from proximal through the rubber cap (2.7) or through the sterile universal sealing valve (2.8) into the working element (2).
 - With the working element (2) in home position, the laser fiber must project at least 5mm from the resectoscope sheath.
- ◇ Let go of pushbutton (2.12).
 - The laser fiber is fixed in the working element (2).



- ◇ Carry out a function check: see section 8.2

7.2 Additional notes and instructions for use

7.2.1 Electrical current



WARNING!

Danger from electric shock!

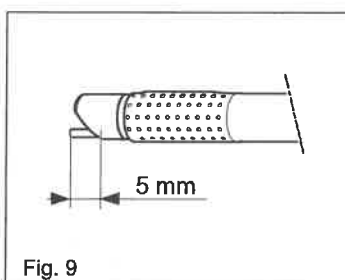
Patient leakage currents can add up if the endoscopes are combined with other powered endoscopic accessories.

Make sure that the combinations do not exceed the permissible patient leakage currents.

7.3 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 the scope's field of view!

Inadvertant tissue damage as well as damage to the distal end of the PAN-OVIEW telescope (3) and instrument parts is possible.

Activate the laser only after

- ✦ *the tip of the laser fiber has become fully visible through the PAN-OVIEW telescope (3) and*
- ✦ *contact is made with the intended treatment area by means of the pilot beam.*

With the working element (2) in home position, the laser fiber must project at least 5 mm from the resectoscope sheath (Fig. 9).



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!

Highly coherent laser beam!

The laser energy may cause injuries in the the user's face around the eyes.

Wear the required personal protection gear when using this product in conjunction with laser devices.

An additional suitable filter attachment is required when using lasers and working with endoscopes under direct view.



CAUTION!

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

Use a suitable filter attachment on the eyepiece of the PANOVIEW telescope (3).

8 Checks



CAUTION!

*Be careful if products are damaged or incomplete!
Injuries of the patient, user and 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.*



IMPORTANT!

For sterile products:

Sterility is only guaranteed if the packaging is undamaged and has not been opened before.

- ◆ Do not use the product if the sterile packaging is damaged or the use-by date is exceeded.

8.1 Visual check

- ◇ Check the instruments and accessories for the following:
 - ◆ damage
 - ◆ sharp edges
 - ◆ loose or missing parts
 - ◆ rough surfaces.
- ◇ Any inscriptions or identification necessary for the safe intended use must be legible.
 - ◆ To prevent wrong handling or reprocessing, any illegible lettering, labeling or identification must be reinstated.

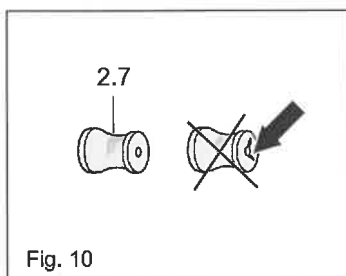


Fig. 10

- ◇ Check the rubber cap (2.7) for damage.
 - ◆ Replace brittle and cracked rubber caps (2.7).

8.1.1 Inner sheath with distal ceramic tip



WARNING!

Danger of injury!

Incorrect use, e.g. fall, shock, blow or similar mechanical loads can cause hairline and / or spalling of ceramic material in the distal area of the inner sheath.

Injuries to the patient, user or third parties are possible.

Observe surface changes and ensure safe handling.

Do not use a damaged inner sheath. Return damaged inner sheath for repair.

Fig. 11

e.g. "Shark" inner sheath (A)

- ◇ The ceramic insulation on the distal end of the inner sheath must be checked for damage before every use.

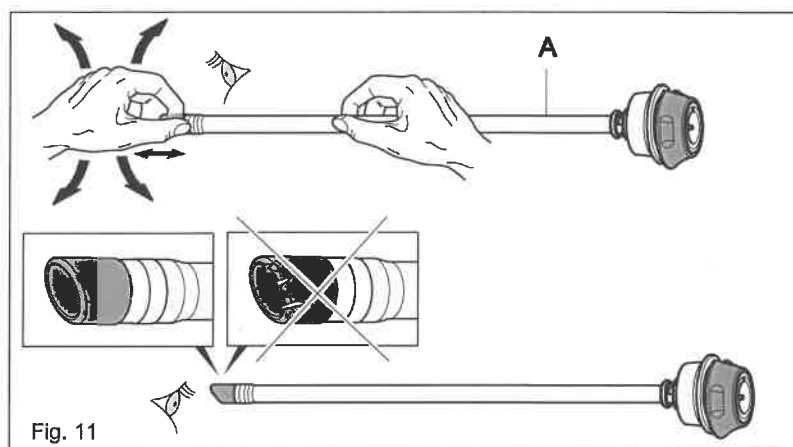


Fig. 11

8.2 Function check

- ◇ Check the individual components for compatibility.
- ◇ Check for secure connections.
- ◇ Check the individual instruments for easy assembly and proper functioning of the locking mechanism(s). Replace the instruments if the connection
 - ✦ although locked is not secure.
 - ✦ cannot be locked or is difficult to lock.
- ◇ Check that the laser fiber can be introduced easily through the probe guide channel (2.11) and the guide tube (1.1).
- ◇ Check the guide tube (1.1) for patency (free passage).
- ◇ Check the irrigation and suction functions.
- ◇ Check image quality
- ◇ Check the entire system for leak-tightness and free passage (patency).

9 Reprocessing and maintenance



WARNING!

Creutzfeldt-Jakob Disease!

If the patient is suspected of having Creutzfeldt-Jakob Disease (CJD) or a variant of the Creutzfeldt-Jakob Disease (vCJD) or the latter have been diagnosed, adequate measures must be taken to prevent possible transmission to other patients, users and third parties.

For this purpose, apply the country-specific reprocessing guidelines and regulations.



IMPORTANT!

The sterile universal sealing valve (2.8) is designed for single use only and must be discarded after each patient use, taking into account the country-specific regulations.

9.1 Disassembly before cleaning

- ◇ Remove the laser fiber.
- ◇ Remove all connections between the resectoscope and the PANOVIEW telescope (3) and the system components.
- ◇ Remove all parts used:
 - Working element (2): see section 7.1.6
 - Continuous-irrigation inner sheath: see section 7.1.4, 7.1.5
 - Guide tube (1): see section 7.1.3
 - PANOVIEW telescope (3): see section 7.1.2

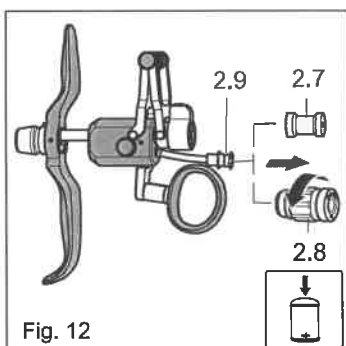


Fig. 12

Fig. 12

- ◇ Remove the rubber cap (2.7).
 - Unscrew and discard the sterile universal sealing valve (2.8) if used.

9.2 Illustrations on reprocessing

IMPORTANT!

The reprocessing of resectoscope sheaths (4) (5) (A) (B), obturator (6) and PAN-OVIEW telescope (3) is described in the corresponding manuals and must be followed.

9.2.1 Manual cleaning

IMPORTANT!

Do not clean the plastic parts with metal or sharp-edged tools (e.g. brushes).

Guide tubes (1), working element (2)

Fig. 13

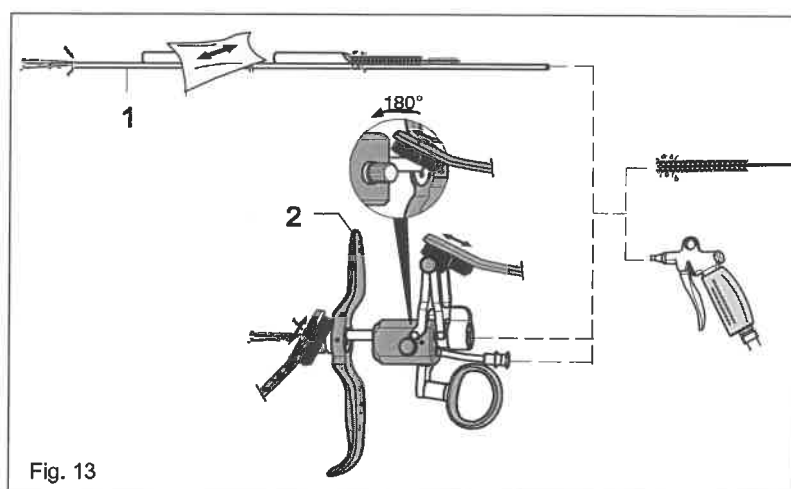


Fig. 13

9.2.2 Machine cleaning

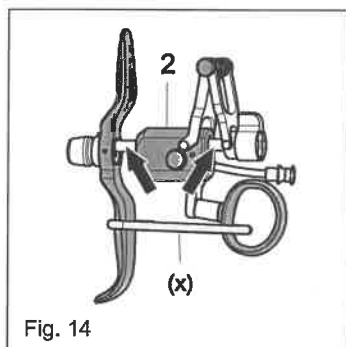


Fig. 14

Working element (2):

Fig. 14

To achieve thorough cleaning in the area of the lock body, avoid any contact between the lock body and the adjacent surfaces.

- ◇ Position a cleaning clamp (x) between the handle and thumb ring to open up and expose areas near the lock body for cleaning.

9.3 Sterilization

9.3.1 Guide tubes for laser fiber (1)

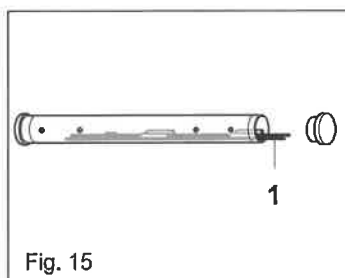


Fig. 15

IMPORTANT!

*To protect the guide tubes for laser fiber (1) we recommend using the sterilization protection sleeve 8428.901
The latter can be equipped with a maximum of 5 guide tubes for laser fibers (1).*

9.4 Reprocessing procedure

The following table describes the reprocessing procedure used by Richard Wolf GmbH for validation.

IMPORTANT!

- ✦ *If used as intended and following the manufacturer's instruction manual, it is not necessary to limit the number of possible reprocessing cycles.*
- ✦ *Careful and gentle handling of medical products during the entire reprocessing process has an essential influence on the service life of the products.*
- ✦ *Before returning defective products for repair, they must have been subjected to the entire reprocessing cycle.*
- ✦ *The user must ensure that the reprocessing process including the resources, materials and staff are suitable to achieve the required results.*
- ✦ *The national and international requirements regarding the validation of the user's reprocessing process must be followed.*

Product:	Guide tubes for laser fiber (1), working element (2)	
Reprocessing guide:		
Preparation at the point of use:	Immediately after use, remove any coarse soiling from the products. If there are more than 6 h between use and reprocessing, rinse out the hollow spaces with a 20 ml syringe filled with water. Do not use any cleaning products (e.g. aldehydes) or hot water (>40°C) for pre-cleaning as this may bake possible residues to the surfaces. May also use a pre-treat spray.	
Transport:	To avoid damage to the products and contamination of the environment, the products must be stored safely in a closed container.	
Pre-cleaning:	Disassembly before cleaning: see section 9.1 No special requirements.	
	Manual	Machine
Cleaning:	See section 9.2.1, Fig. 13 1. Clean / rinse out the guide channel on the locking cone (2.1), receptacle (2.14) and probe guide channel (2.11) with a 5 ml syringe filled with an enzymatic cleaning solution. 2. Immerse in an enzymatic cleaning solution for at least 5 minutes, then brush inside. 3. Brush the outside of the working element (2), in particular in the area of the lock body (2.2) and the receptacle (2.14), with a soft brush for at least 5 seconds to remove any residues. 4. At the end, rinse the working element (2) for at least 20 seconds. 5. Rinse out the lumens with 3 pressure surges (2.5 - 4 bar) using a cleaning gun. 6. Rinse the outer surfaces with water under the tap.	1. Before machine cleaning, preclean the instruments manually. ♦ see section 9.2.1, Fig. 13 2. Attach the cleaning clamp (x) to the handle parts of the working element (2). ♦ see section 9.2.2, Fig. 14 3. Connect the working element (2) via the luer fitting (2.9) to the washer-disinfector rack using a suitable tube system. ♦ >4 min. of pre-washing with cold water ♦ Empty ♦ >6 min of washing with a cleaning agent at 55°C ♦ Empty ♦ >3 min of neutralization*) using warm tap water (<40°C) ♦ Empty ♦ >2 min of intermediate rinsing using hot tap water (<40°C) ♦ Empty
Disinfection:	1. Dry the instruments to prevent dilution of the disinfectant solution. 2. Immerse the products in an approved disinfectant solution, allow to soak as specified by the manufacturer. 3. At the end, thoroughly rinse the products with processed water**) for at least 20 seconds.	Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).
Drying:	Manual drying: Dry the products outside using a lint-free disposable cloth or swab, or, alternatively, in a drying cabinet. Dry hollow spaces with filtered compressed air.	Drying of instruments in the drying cycle of the washer-disinfector. If necessary, additional drying can be achieved manually using a lint-free disposable cloth or swab or, alternatively, in a drying cabinet. Dry hollow spaces with filtered compressed air.
Function check, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. ♦ Carry out a visual check: see section 8.1	
Packaging:	Package the products for sterilization as required by the valid standards.	
Sterilization:	Sterilize the products using the fractional pre-vacuum procedure (ISO17665) taking into account the applicable national requirements. ♦ Temperature exposure time: 4 minutes at 134°C +4°C (273°F +7°F) 132°C +4°C (270°F +7°F) only for USA ♦ Evacuation: 3 x ♦ Drying time: 20 - 30 min ♦ Maximum sterilization temperature: 138°C For further reprocessing procedures: see section 9.5	
Storage:	Store the sterilized instruments in a restricted area at approximately 24C / 75F, with at least 4 air exchanges per hour and a relative humidity that does not exceed 70%, in accordance with ANSI/AAMI St79.	
Validation:	To validate reprocessing the following materials and machines were used:	

Product:	Guide tubes for laser fiber (1), working element (2)		
Reprocessing guide:			
Validation:	Manual		
	‣ Cleaning agent:	Cleaner 0.5% neodisher MediClean (Dr. Weigert)	
	‣ Disinfectant:	Cidex (Advanced Sterilization Products)	
	Machine		
	‣ AWD:	Miele G7735CD	
	‣ Rack:	Miele E 440/1	
	‣ Program:	Vario-TD	
	‣ Cleaning agent:	Cleaner 0.5% MediClean (Dr. Weigert)	
	Sterilization		
‣ Sterilizer:	Selectomat HP 666-1 HRED (MMM)		
Additional instructions:	It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer specifications.		

*^a) depending on the quality of the neutralization solution, add an acid based on citric acid.

**^b) use sterile water if manual disinfection is not followed by sterilization.

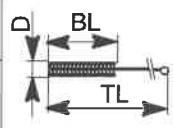
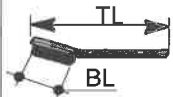
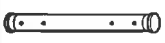
9.5 Alternate sterilization methods

- ◇ 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

Item	Illustration	Product no.	Designation, Technical data
2		8654.282	Working element for telescope Ø = 4,0 mm
1		8654.981	Guide tube for laser fiber Overall length = 265 mm; Passage 1000 µm
		8654.982	Guide tube for laser fiber for urethra slitting Overall length = 268 mm; Passage 550 µm
		8654.985	Guide tube for laser fiber Overall length = 265 mm; Passage 600 µm
		8654.986	Guide tube for laser fiber with distal loop Overall length = 268 mm; Passage 600 µm
		8654.987	Guide tube for laser fiber Overall length = 265 mm; Passage 550 µm

11 Spare parts and accessories

Item	Illustration	Product no.	Designation, Technical data
2.8		4712348	Sterile universal sealing valve for the introduction of auxiliary instruments from 1 - 6 Fr. Packaging unit = pack of 5
2.7		88.005	Rubber cap "RIWO" red, for instruments up to 5 Fr. Packaging unit = pack of 10
		88.01	Rubber cap "RIWO" red-orange, for instruments up to 7 Fr. Packaging unit = pack of 10
-		40606	Disposable cleaning brush Total length TL = 305 mm; Brushes (Ø) D = 5 mm; Brush length BL = 50 mm Packaging unit = pack of 10
-		40604	Disposable cleaning brush Total length TL = 400 mm; Brushes (Ø) D = 2 mm; Brush length BL = 50 mm Packaging unit = pack of 10
-		409990012	Disposable cleaning brush Total length TL = 147 mm; Brush length BL = 42 mm Packaging unit = pack of 3
-		8428.901	Sterilization protection sleeve holding a maximum of 5 guide tubes for laser fibers
-		6199.00	Water cleaning pistol with 8 attachments and storage rack

The products can be combined as required provided the relevant technical data and intended uses are observed. For a general overview please refer to the latest catalog pages, 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
Disposable items, sterile products	Follow instructions on package !



IMPORTANT!

*Store sterile products in the original packaging until use.
Incorrect storage may lead to loss of sterility.*



IMPORTANT!

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 valid 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.

