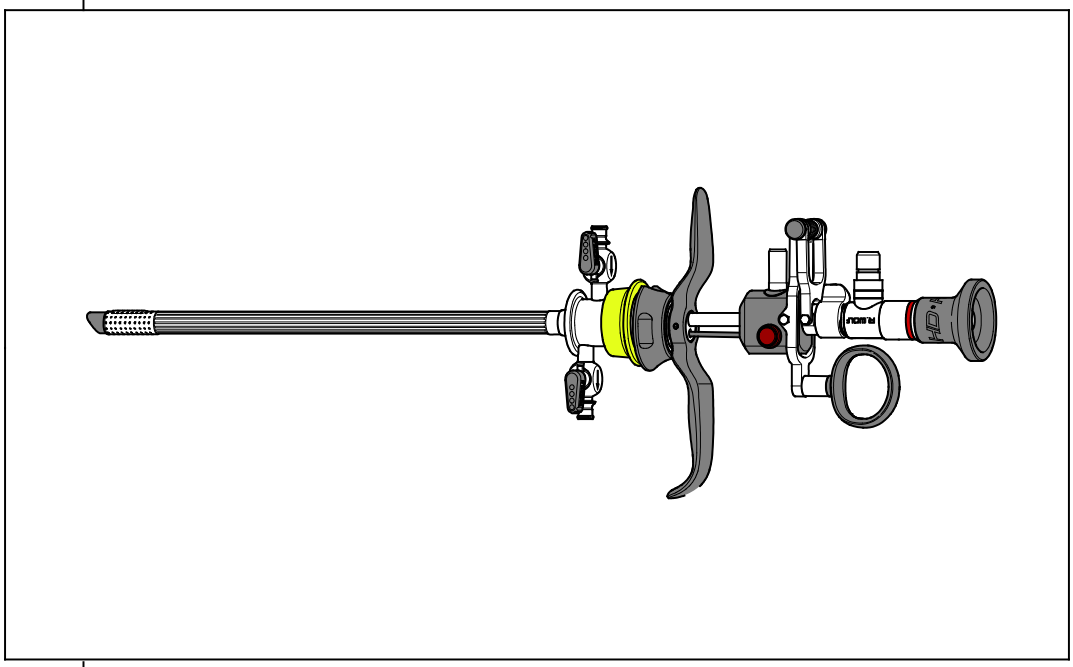
Instruction Manual



Shark

Resectoscopes

with Continuous-Irrigation Double-Sheath System

with Intermittent Irrigation

GA-D 366 / USA / 2014-01 V2.0 / ECO 2013-0344 (RW: 2013-12 V3.0 / PDI 13-7069)

⚠ 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!*** ***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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Contents

1 Technical description

"Shark" resectoscopes are used for **T**rans**u**rethral **R**esection of the **P**rostate (**TURP**) and **T**rans**u**rethral **R**esection of **B**ladder tumors (**TURB**) in the lower urinary tract and consist of:

◇ **PANOVIEW telescopes (endoscopes)**
- PANOVIEW 0°, 12° and 30° telescopes

◇ **Resectoscope sheaths**
- Resectoscope sheaths, rotatable
- Resectoscope sheaths, non-rotatable

◇ **Obturators**
- Obturator
- Viewing obturator
- Dilation obturator

◇ **Working elements**
- Working element, active: Cutting is effected actively with spring-assisted release
- Working element, passive: Cutting is effected by spring pressure

◇ **Electrodes**
- Single-use electrodes, monopolar, sterile (disposable)

2 Intended use

"Shark" resectoscopes are used for endoscopically controlled tissue ablation.

These products are exclusively intended for use by medical staff and may only be used by medically qualified and adequately trained doctors.

2.1 PANOVIEW telescopes (endoscopes)

are used to visualize the inside of the patient via natural passages.

2.2 Obturators

are used for atraumatic insertion of the resectoscope sheath into the urethra.

◇ **Viewing obturator**
- is used for housing and fixation of the PANOVIEW telescope
- is used for atraumatic insertion of the resectoscope sheath into the urethra under visual control

◇ **Dilation obturator**
- is used for atraumatic insertion of the resectoscope sheath into the urethra by dilating the distal flexible obturator piston via the control lever.

2.3 Working elements

They hold and lock in place the PANOVIEW telescope and the electrode and allow controlled insertion of the electrode into the operating field under visual control.

2.4 Electrodes

are used for ablating, severing, cutting and coagulating soft tissue

◇ **Single-use electrodes**
- for combined cutting / coagulation

With regard to their reprocessing / reusability, the electrodes are distinguished as follows:

◇ **Single-use electrodes, monopolar,** sterile (disposable)

- Identification feature: the product numbers start with **"4"**
  example: **4**6782235

2.5 "Shark" resectoscope continuous-irrigation double-sheath system A

◇ **Inner sheath**

- holds and automatically locks the outer sheath and the working element
- establishes the rotatable connection between the inner sheath and outer sheath with working element, PANOVIEW telescope and electrode

◇ **Outer sheath**

- houses and automatically fixes the inner sheath and a provides rotatable support for the inner sheath
- provides continuous irrigation fluid supply
- allows drainage or aspiration of irrigation fluid

2.6 "Shark" resectoscope with intermittent irrigation B C

2.6.1 "Shark" resectoscopes with rotatable adapters B

◇ **B1 - Resectoscope sheath with luer fitting**

◇ **B2 - Resectoscope sheath with luer stopcock**

◇ **Resectoscope sheath**

- houses and automatically fixes the rotatable irrigation adapter
- establishes the connection between the resectoscope sheath and working element with PANOVIEW telescope and electrode

◇ **Rotatable irrigation adapter (B1)**

- allows continuous irrigation fluid supply via luer fitting

◇ **Rotatable irrigation adapter (B2)**

- allows controllable irrigation fluid supply via the irrigation stopcock

2.6.2 "Shark" resectoscopes with central stopcock non-rotatable C

◇ **Sheath with central stopcock**

- allows continuous irrigation fluid supply (stopcock plug in the "IN" position)
- is used for maintaining the irrigation fluid once the bladder capacity has been reached (stopcock plug in the "0" position)
- allows drainage or aspiration of irrigation fluid (stopcock plug in the "OUT" position)

◇ **Adapter**

- houses and automatically fixes
  - the sheath with central stopcock
  - the working element with PANOVIEW telescope and electrode

3 Indications and field of application

The product is used for minimally invasive diagnosis and / or therapy in conjunction with PANOVIEW telescopes and / or endoscopic accessories in the various medical disciplines such as

- ◇ Urology
- ◇ Gynecology
- ◇ Surgery

Application:

- ◇ Transurethral resection of the prostate (TURP)
- ◇ Transurethral resection of bladder tumors (TURB)
- ◇ Adenomas and soft-tissue tumors
- ◇ Slitting of the neck of the bladder and incision of the prostate
- ◇ Myoma resection and endometrial ablation

4 Contraindications and side effects

4.1 Contraindications

Contraindications directly related to the product are presently unknown. On the basis of the latest state of the art in medicine and the patient's condition, the doctor in charge must decide whether the planned application is possible or not.

With regard to sex, provenience, anamnesis and other framework conditions, the patient selection for the application of the described medical product is not restricted.

4.2 Side effects

Side effects are not known if instruments are applied as specified in the intended use.

5 Combinations

“Shark“ resectoscopes are used in conjunction with:

- ◇ Light projectors and fiber light cables
- ◇ HF surgical devices
- ◇ Pumps for irrigation or suction
- ◇ 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 used together if their intended uses and the relevant technical data (working length, diameter, peak voltage, etc.) are the same.

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

Follow the "Notes and instructions on HF applications", order no.: GA-S 002 as well as the HF device manufacturer's instructions.

⚠ *CAUTION!*

Do not use electrodes made by other manufacturers.

5.1 System overview of “Shark“ resectoscopes

For this, see brochure BB-D366, System overview of “Shark“ resectoscopes.

“Shark” resectoscope sheaths can also be used in conjunction with bipolar working elements 8680.xxx.

➧ For this, also see the supplement BB-D342, System Overview of *„S-line“* *S(a)line* resectoscopes.

6 Illustration

6.1 Resectoscope sheaths (continuous-irrigation double-sheath system) A

Resectoscope sheaths (intermittent irrigation) B C

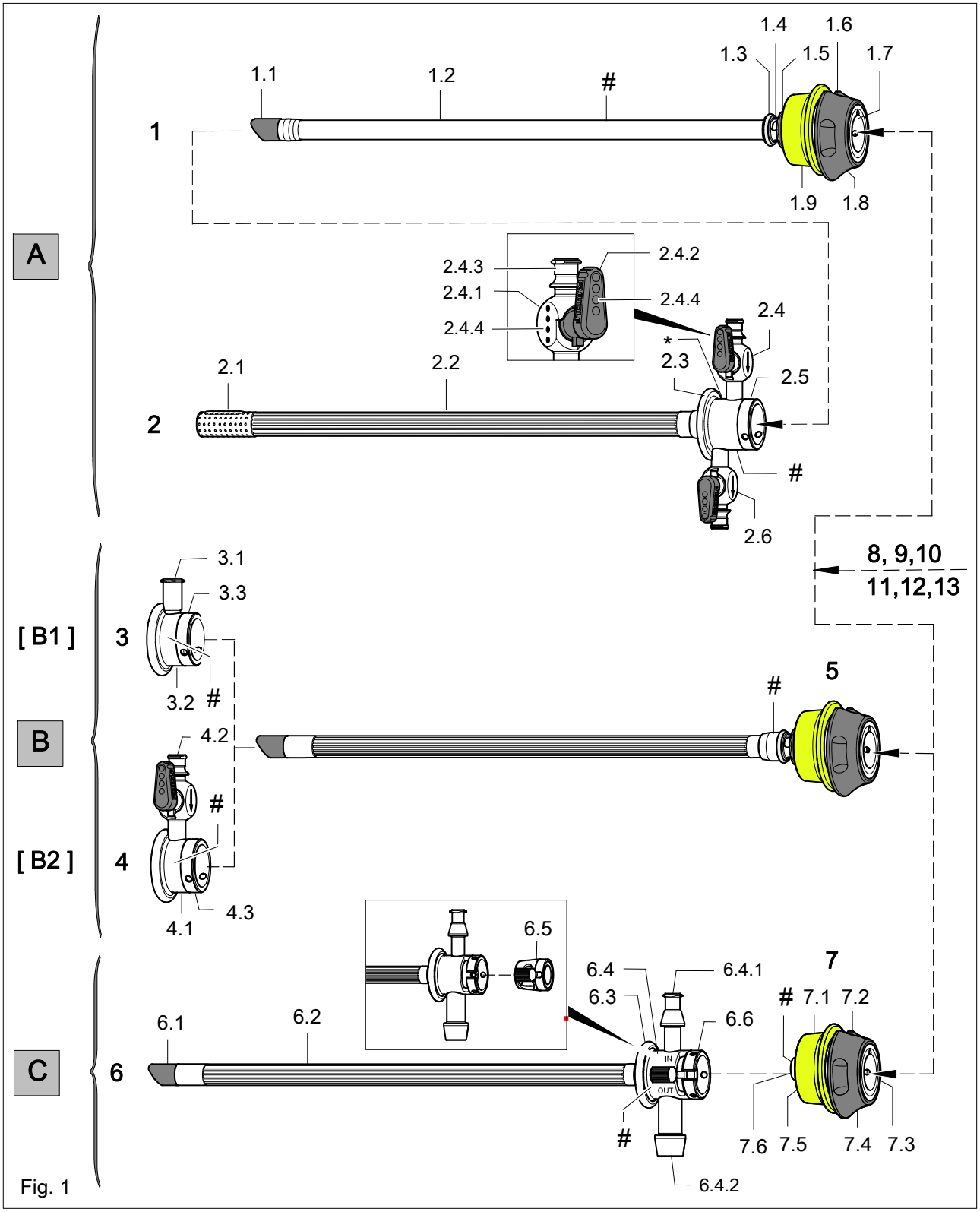


Fig. 1

6.1.1 Legend and identification

Item	Designation	"Shark" resectoscopes			
		A	B		C
			[B1]	[B2]	
		rotatable			non-rotatable
1	**Inner sheath**	■	■	■	□
1.1	Insulating insert (ceramic tip)	■	■	■	□
1.2	Sheath tube	■	■	■	□
1.3	O-ring	■	■	■	□
1.4	Irrigation holes	■	■	■	□
1.5	O-ring	■	■	■	□
1.6	Recess (for orientation)	■	■	■	□
1.7	Lock body	■	■	■	□
1.8	Actuation ring	■	■	■	□
1.9	External ring with color coding	■	■	■	□
2	**Outer sheath**	■	□	□	□
2.1	Drain holes (suction holes)	■	□	□	□
2.2	Sheath tube	■	□	□	□
2.3	Flange	■	□	□	□
2.4	Irrigation stopcock, complete	■	□	□	□
2.4.1	Stopcock housing	■	□	□	□
2.4.2	Stopcock plug	■	□	□	□
2.4.3	Luer fitting	■	□	□	□
2.4.4	Identification for passage on - stopcock housing - stopcock plug	■	□	□	□
2.5	Ball catch	■	□	□	□
2.6	Drain stopcock, complete (see 2.4)	■	□	□	□
3	**Rotatable irrigation adapter**	□	■	□	□
3.2	Rotatable irrigation ring	□	■	□	□
3.1	Luer fitting	□	■	□	□
3.3	Ball catch	□	■	□	□
4	**Rotatable irrigation adapter**	□	□	■	□
4.1	Rotatable irrigation ring	□	□	■	□
4.2	Luer stopcock, complete (see 2.4)	□	□	■	□
4.3	Ball catch	□	□	■	□
5	**Resectoscope sheath** (other items as under 1)	□	■	■	□
6	**Resectoscope sheath with central stopcock**	□	□	□	■
6.1	Insulating insert (ceramic tip)	□	□	□	■
6.2	Sheath tube	□	□	□	■
6.3	Flange	□	□	□	■
6.4	Retainer body, complete	□	□	□	■
6.4.1	Luer fitting "IN"	□	□	□	■
6.4.2	"OUT" connector	□	□	□	■
6.5	Stopcock plug	□	□	□	■
6.6	Ball catch	□	□	□	■

■ = applicable □ = not applicable

Item	Designation	"Shark" resectoscopes			
		A	B		C
			[B1]	[B2]	
		rotatable			non-rotatable
7	**Adapter**	☐	☐	☐	■
7.1	Outer ring with color coding	☐	☐	☐	■
7.2	Recess (for orientation)	☐	☐	☐	■
7.3	Sleeve	☐	☐	☐	■
7.4	Actuation ring	☐	☐	☐	■
7.5	O-ring	☐	☐	☐	■
7.6	Lock body	☐	☐	☐	■
*	Fr. indication	■	■	■	■
#	Product no.	■	■	■	■

■ = applicable ☐ = not applicable

6.2 Obturators, working elements and electrodes

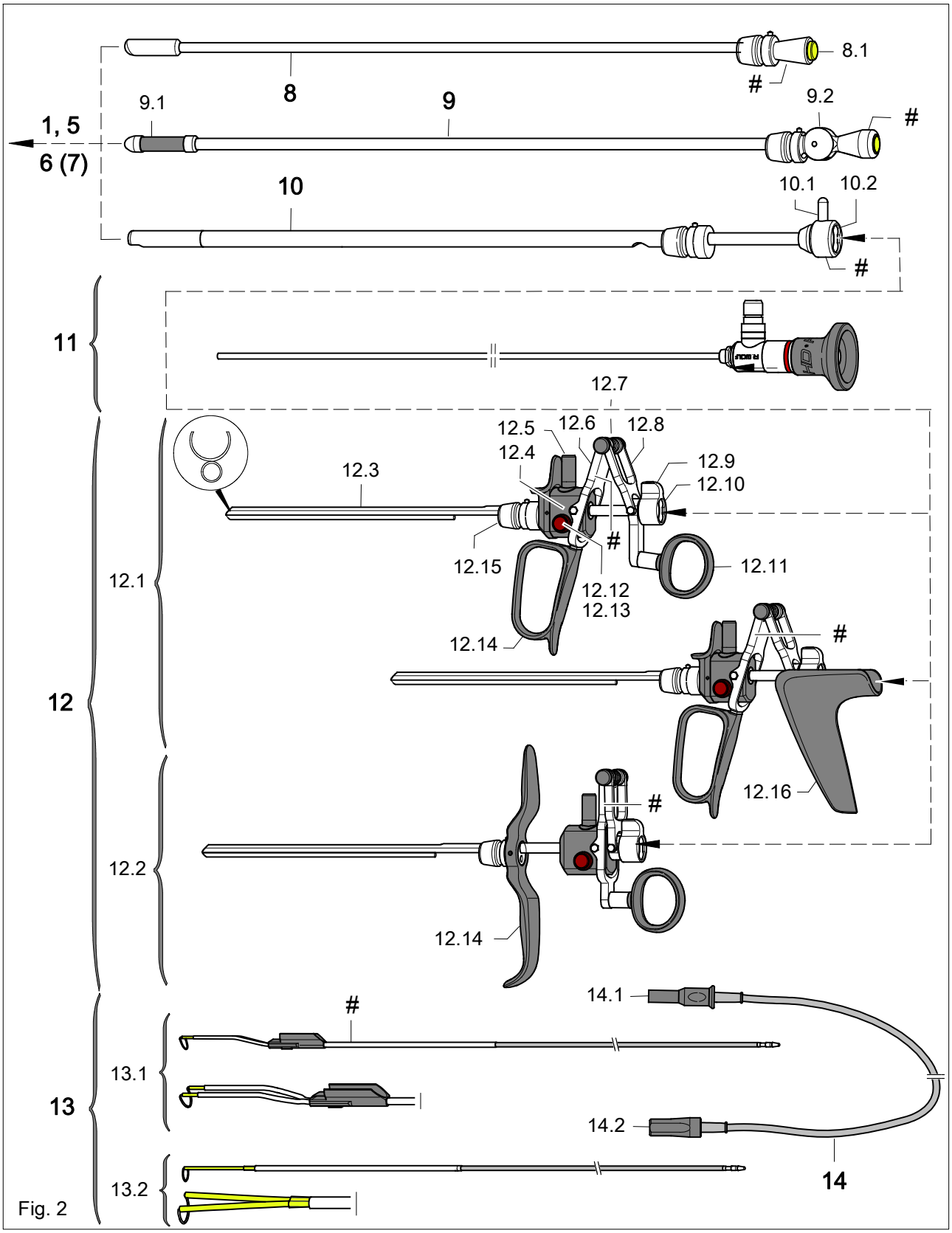


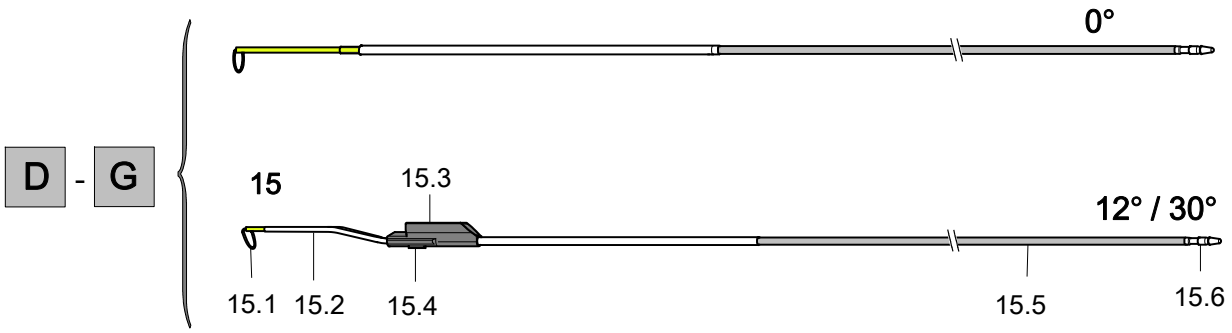
Fig. 2

6.2.1 Legend and identification

Item	Designation	Item	Designation
8	**Obturator**	**12**	**Working element** Telescope guide tube, semi-circular, open
8.1	Handle with color coding	12.1	**Working element, active** Cutting action with spring assisted release, grip closed
9	**Dilation obturator**	12.2	**Working element, passive** Cutting action with spring assisted cutting, grip open
9.1	Dilatable obturator piston	12.3	Guide rail
9.2	Inclinable handle with color coding	12.4	Lock body
10	**Viewing obturator**	12.5	HF connector
10.1	Locking lever with color coding	12.6	Arm, front
10.2	Locking ring	12.7	Spring
11	**Endoscope**	12.8	Arm, rear
		11.9	Locking lever
		12.10	Locking ring
		12.11	Thumb ring
		12.12	Pushbutton
		12.13	Cap
		12.14	Grip
		12.15	Locking cone
		12.16	Thumb support
		13	**Single-use electrodes,** sterile See figure 3
		13.1	Electrodes for 4 mm, 12° / 30°
		13.2	Electrodes for 4 mm, 0°
		14	**Monopolar HF connection cable**
		14.1	Connector to device for connection to HF surgical device
		14.2	Connector to instrument for connection to HF connector (12.5)
		#	Product no.

6.3 Electrodes, monopolar

6.3.1 Single-use electrodes, sterile (disposable) D - G



D - G

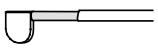
Item	0°	12° / 30°
D		
E1		
E2	-	
E3	-	
F		
G1	-	
G2		-

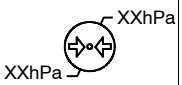
Fig. 3

6.3.2 Legend and identification

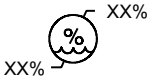
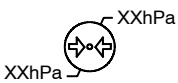
Item	Designation	Item	Designation
15	**Electrode structure**		
15.1	Electrode head	15.5	Proximal insulation (stem)
15.2	Distal insulation (fork) Color coding: ◗ **green** for 22 / 24 Fr. resectoscope sheath ◗ **yellow** for 24 / 26 Fr. resectoscope sheath ◗ **black** for 26 Fr. resectoscope sheath	15.6	Contact section
15.3	Telescope guide, black (plastic part)		
15.4	Guide nose ◗ **without** guide nose - color coding **green** for 22 Fr. inner sheath ◗ **with** guide nose - 1st step - color coding **yellow** for 24 Fr. inner sheath ◗ **with** guide nose - 2nd step - color coding **black** for 26 Fr. inner sheath	#	**Product no.** ◗ **on sterile packaging** Single-use electrodes, sterile
D - G	**Single-use electrodes, sterile**		
16	**Electrode shapes**		
D	**Cutting electrode, loop**	**F**	**Hook electrode**
E1	**Coagulation electrode, roller**	**G1**	**Blade electrode**
E2	**Coagulation electrode, sphere**	**G2**	**Blade electrode**
E3	**Coagulation electrode, button**		

6.4 Symbols

6.4.1 Reprocessable products (unsterile)

Symbol	Designation
	Attention, Caution
	Follow the instruction manual
	Observe the instruction manual
	Order number
	Lot designation
	Serial no.
	Unsterile
	Manufacturer
	Limitation of atmospheric pressure
	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).

6.4.2 Disposable products (sterile)

Symbol	Designation
	Follow the instruction manual
	Observe the instruction manual
REF	Order number
LOT	Lot designation
	Manufacturing date
Σ	Quantity
	To be used before:
	Do not reuse.
	Do not re-sterilize
STERILE EO	Sterilized with ethylen oxide
	Manufacturer
	Do not use if package is damaged!
	Protect against the sun during storage
	Temperature range
	Humidity limitation
	Limitation of atmospheric pressure
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 Use

⚠ *WARNING!*
Do not reprocess disposable items!
The service life of products marked as disposable, i.e. for 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, a deterioration of the product quality cannot be excluded, which will endanger the patient, the user and others.
Possible dangers and risk factors are:

- *strength problems*
- *damage to the product*
- *considerable impairment of function*
- *significantly increased risk of infection*
- *biocompatibility problems*

If a disposable item is reprocessed the product responsibility lies with the user or the person in charge of reprocessing.
In this case the manufacturer can no longer guarantee product safety and performance.

⚠ *CAUTION!*
The products have only limited strength!
Applying excessive force will lead to damage, impair the function and 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.

7.1 Preparation

For the different resectoscopes, the following preparatory measures must be carried out:

◇ Check assembly: see section 9.5
◇ Carry out a check: see sections 8 and 8.1

7.1.1 Inserting inner sheath (1) in outer sheath (2) A

Fig. 4

Locking:

◇ Check that the O-rings (1.3) (1.5) on the inner sheath (1) are in place.
◇ Insert the inner sheath (1) into the outer sheath (2) as far as it will go.
  ➧ The outer sheath (2) snaps audibly onto the inner sheath (1) and is held automatically by a ball catch (2.5).
◇ Check that the rotatable connection is securely connected.

Unlocking:

◇ Push the outer ring (1.9) on the inner sheath (1) in direction of arrow as far as it will go, hold and remove the outer sheath (2).

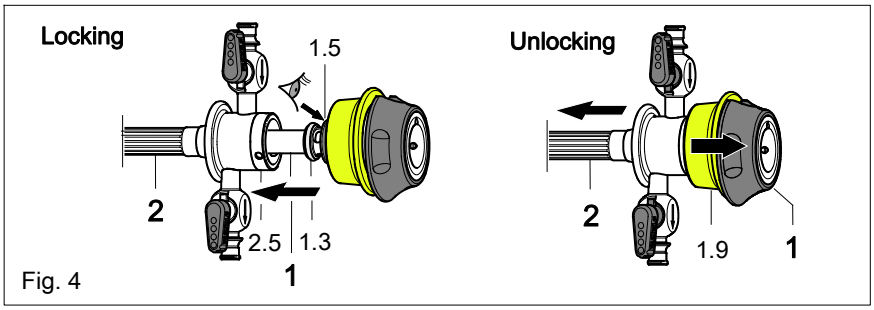


Fig. 4

7.1.2 Attaching the rotatable irrigation adapter (3) or (4) to the resectoscope sheath (5) B

"Shark" resectoscope, rotatable **[B1], [B2]**

Fig. 5

Locking:

◇ Check that the O-rings (1.3) (1.5) are installed on the resectoscope sheath (5).

◇ Insert the resectoscope sheath (5) into the rotatable irrigation adapter (3) or (4) as far as it will go.

➧ The rotatable irrigation adapter (3) or (4) audibly snaps into the resectoscope sheath (5) where it is automatically held by means of the ball catch (3.3) (4.3).

◇ Check that the rotatable connection is securely connected.

Unlocking:

◇ Slide outer ring (1.9) on the resectoscope sheath (5) in direction of arrow as far as it will go, hold and remove the rotatable irrigation adapter (3) or (4).

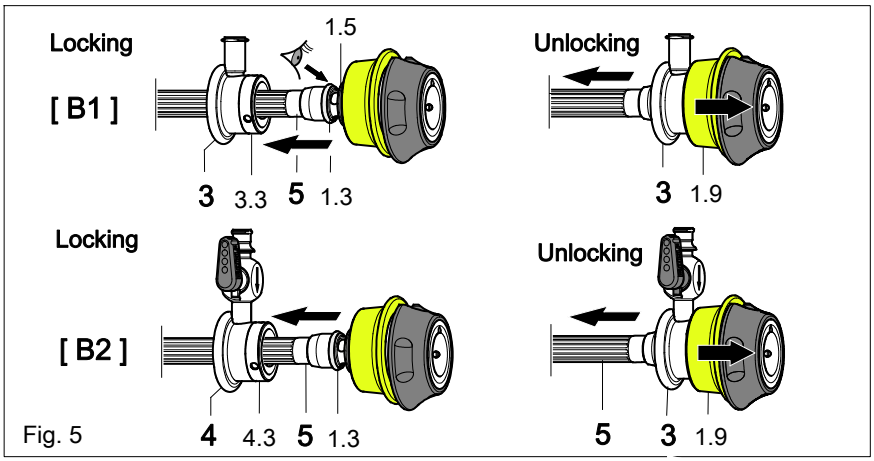


Fig. 5

7.1.3 Attaching the stopcock plug (6.5) and adapter (7) to the non-rotatable resectoscope sheath with central stopcock (6) C

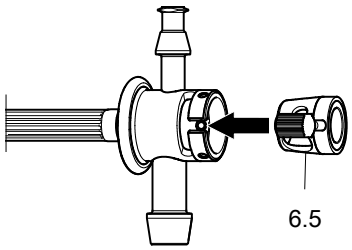


Fig. 6

Fig. 6

◇ Insert the stopcock plug (6.5) in direction of arrow as far as it will go.

Fig. 7

Locking:

◇ Check that the O-ring (7.5) is installed on the adapter (7).

◇ Position the adapter (7) radially to the resectoscope sheath with central stopcock (6) in the snap-in position.

➧ The groove (a) and the pin (b) are aligned.

◇ Slide the resectoscope sheath with central stopcock (6) into the adapter (7) as far as it will go.

➧ The resectoscope sheath with central stopcock (6) clicks audibly into the adapter (7) where it is held automatically by means of the ball catch (6.6).

◇ Check the components for secure connection.

Unlocking:

◇ Slide the outer ring (7.1) on the adapter (7) in direction of arrow as far as it will go, hold and remove the resectoscope sheath with central stopcock (6).

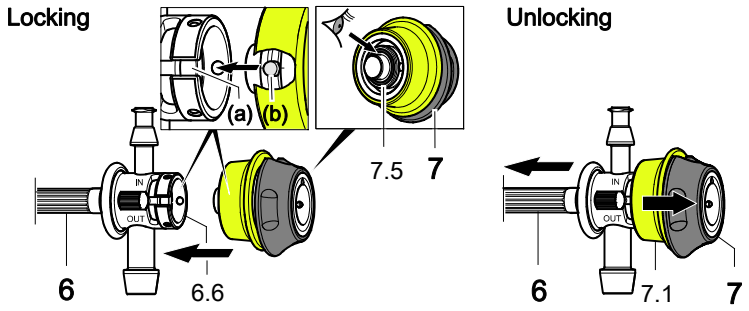


Fig. 7

7.1.4 Orientation when installing the instruments

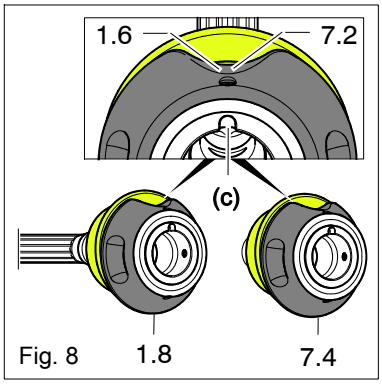


Fig. 8

Fig. 8

☞ ***NOTE!***

The actuation ring (1.8) (7.4) has a recess (1.6) (7.2) located opposite of the groove (c).

When inserting the obturators (8) (9) (10) and the working element (12), the groove (c) of the actuation ring (1.8) (7.4) and the pin (d) of the instruments must be aligned.

The recess (1.6) (7.2) provides orientation.

7.1.5 Inserting obturator (8) into resectoscope sheath

Fig. 9

Locking:

◇ Insert the obturator (8) into the resectoscope sheath in such a way that the groove (c) and the pin (d) are aligned.
Push together until the obturator (8) engages automatically in the lock body (1.7) or (7.6).

◇ Check the components for secure connection.

☞ ***NOTE!***

If the obturator (8) won't engage in the lock body (1.7) or (7.6), press the acutation ring (1.8) or (7.4) in direction of arrow as far as it will go and repeat the procedure.

Unlocking:

◇ Push the actuation ring (1.8) or (7.4) in direction of arrow as far as it will go and remove the obturator (8).

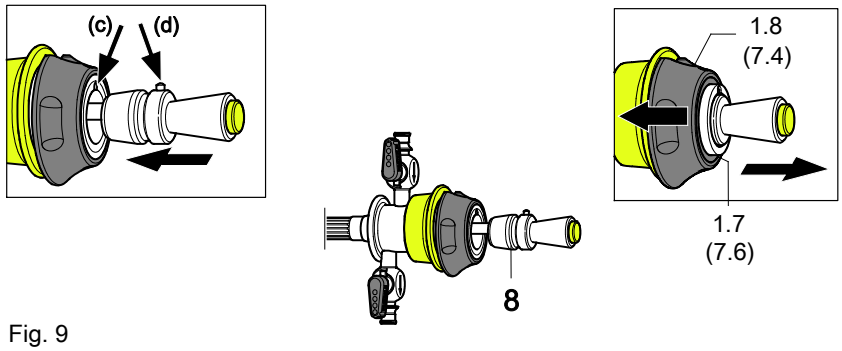


Fig. 9

7.1.6 Inserting dilation obturator (9) in resectoscope sheath

Fig. 10

☞ ***IMPORTANT!***

Insert or withdraw the dilation obturator (9) into / from the resectoscope sheath only when the inclinable handle (9.2) is horizontal.

Locking and unlocking:

◇ Same procedure as described under section 7.1.5.

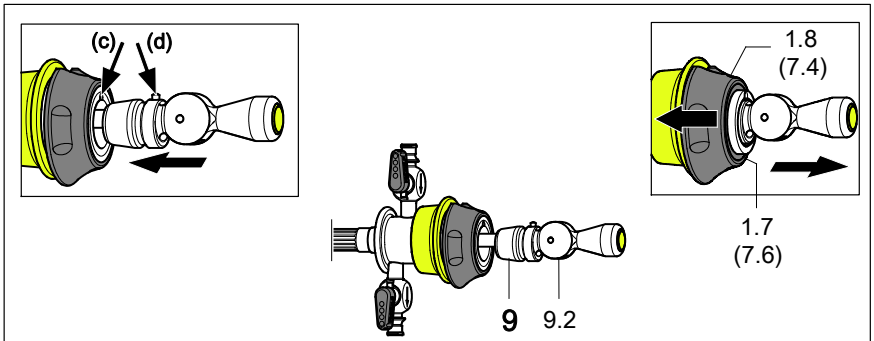


Fig. 10

Fig. 11

Dilating the flexible obturator piston (9.1)

◇ Angle the inclinable handle (9.2) to the 90° position.
  ◗ The handle (9.2) is locked in this end position.

☞ ***IMPORTANT!***

The dilatable obturator piston is only conically dilated creating an atraumatic transition between the obturator tip and the end of the sheath when the handle is in the end position.

◇ Check dilation of obturator piston (9.1).
◇ Do not use the dilation obturator (9).
  ◗ if it is not possible to move the inclinable handle (9.2) to its end position.
  ◗ if damage (e.g. cracking) has occured on the dilatable obturator piston (9.1).

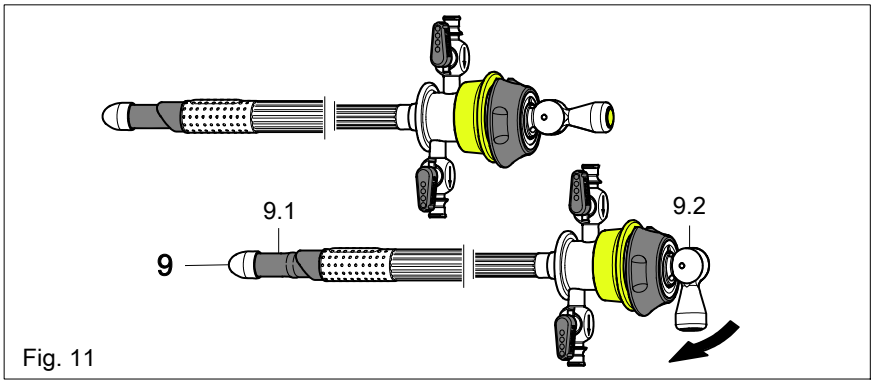


Fig. 11

7.1.7 Inserting PANOVIEW telescope (11) into viewing obturator (10)

Fig. 12

The locking lever (10.1) must be in position “I".

Locking:

◇ Insert the PANOVIEW telescope (11) into the viewing obturator (10).
  ◗ The pin (e) engages in the groove (f).
◇ Turn the locking lever (10.1) to position "II".
  ◗ Both components are locked together.
◇ Check the components for secure connection.

The clamping lever (10.1) must be in position “II".

Unlocking:

◇ Turn the locking lever (10.1) to position "I".
  ◗ The locking mechanism is unlocked.
◇ Remove the PANOVIEW telescope (11).

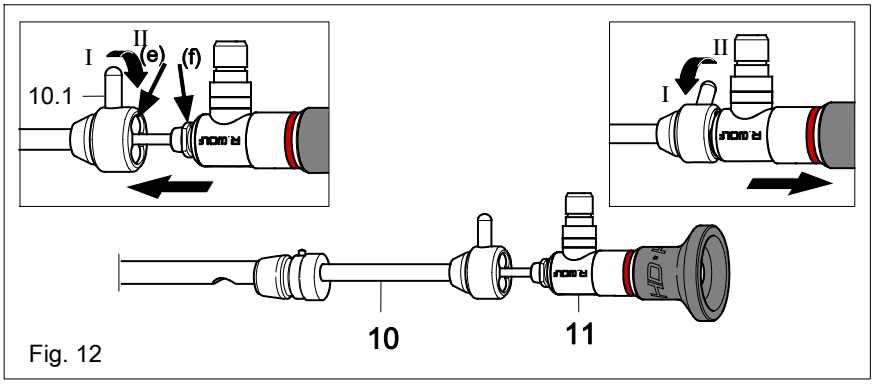


Fig. 12

7.1.8 Inserting viewing obturator (10) with PANOVIEW telescope (11) into the resectoscope sheath

Fig. 13

Locking and unlocking:

◇ Same procedure as described under section 7.1.5.

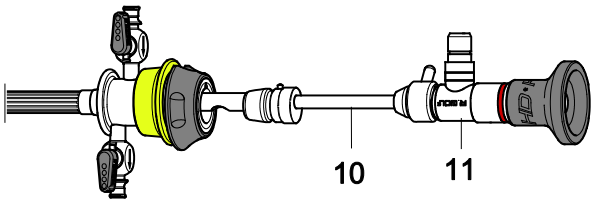


Fig. 13

7.1.9 Inserting the PANOVIEW telescope (11) into the working element (12)

Fig. 14

◇ Same procedure as described under section 7.1.7.

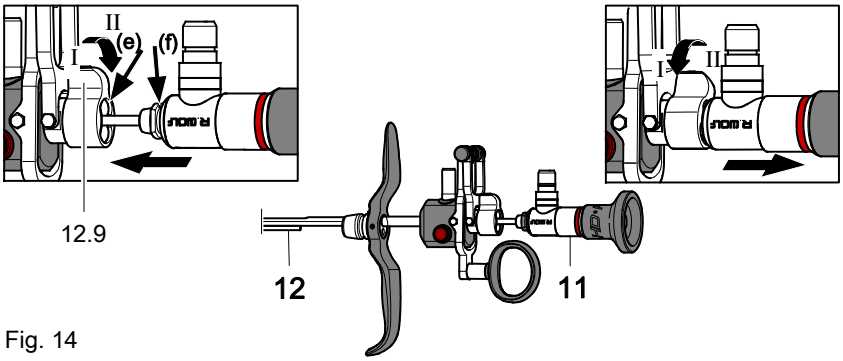


Fig. 14

7.1.10 Inserting electrode (13) into working element (12)

☞ ***IMPORTANT!***

Observe compatibility of the electrodes (13) and the resectoscope sheath.
In the following additional features for compatibility are listed (for this also see section 10):

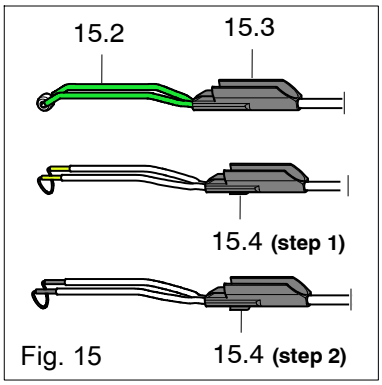


Fig. 15

Fig. 15

Use with cutting electrode

- ***without guide nose (15.3) (15.4) - color coding: green (15.2)***
  only compatible in conjunction with 22 / 24 Fr. continuous-irrigation resectoscope sheath or
  22 Fr. intermittent resectoscope sheath
- ***with guide nose (15.4) - 1st step - color coding: yellow (15.2)***
  only compatible in conjunction with 24 / 26 Fr. continuous-irrigation resectoscope sheath or
  24 Fr. intermittent resectoscope sheath
- ***with guide nose (15.4) - 2nd step - color coding: black (15.2)***
  only compatible in conjunction with 26 Fr. intermittent resectoscope sheath

Use with coagulation electrode / blade electrode / hook electrode

- ***without guide nose (15.3) (15.4) - color coding: green (15.2)***
  compatible in conjunction with resectoscope sheath up to 24 Fr.
- ***with guide nose (15.4) - 1st step - color coding: yellow (15.2)***
  compatible in conjunction with resectoscope sheath from 24. Fr

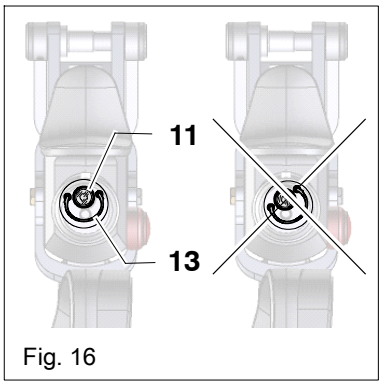


Fig. 16

Fig. 16 / Fig. 17

Locking:

◇ Hold the electrode (13) as shown in Fig. 17 and insert via the guide rail (12.3) into the lock body (12.4) as far as it will go.
  ◗ You can feel the electrode snap into place.
◇ Center the electrode (13) to the PANOVIEW telescope (11) as shown in Fig. 16.
◇ Check firm connection of electrode (13) by pulling slightly.

Unlocking:

◇ Press the button (12.12) and pull out the electrode (13) by holding it by the telescope guide (15.3).

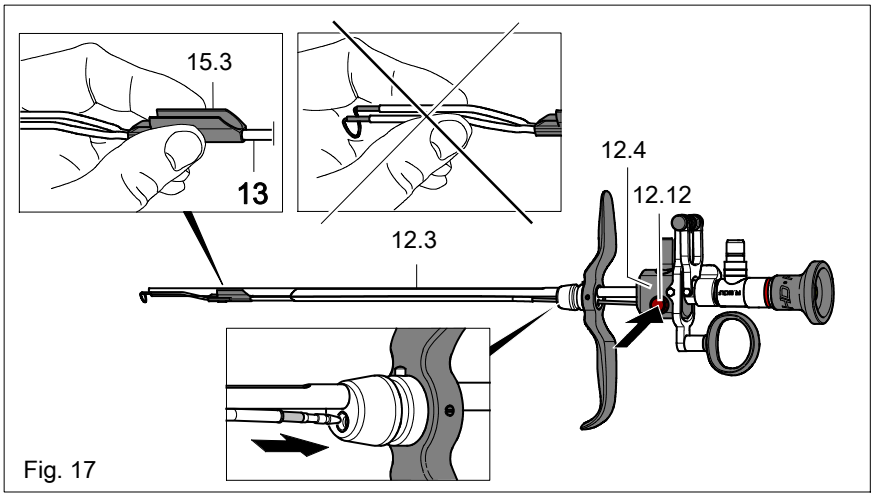


Fig. 17

7.1.11 Inserting working element (12) in resectoscope sheath

Locking and unlocking:

◇ Same procedure as described under section 7.1.5.

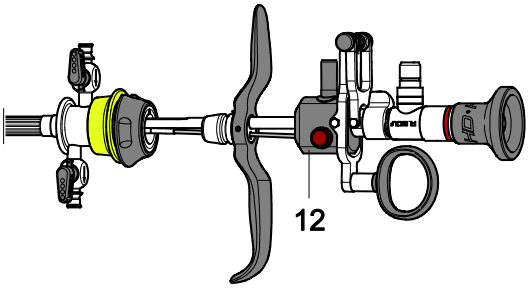


Fig. 18

7.2 Additional notes and instructions for use

7.2.1 Connecting the resectoscope sheath to the suction and irrigation system

◇ Check the suction and irrigation function of the preassembled instrument set as well as the entire system for leak-tightness and patency (free passage) before each use.

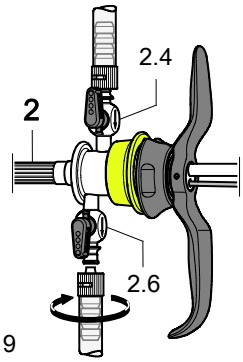


Fig. 19

Resectoscope sheaths (continuous-irrigation double-sheath system) A

Outer sheath (2)

Fig. 19

◇ Connect the irrigation and drain tubes to the irrigation stopcock (2.4) and drain stopcock (2.6).

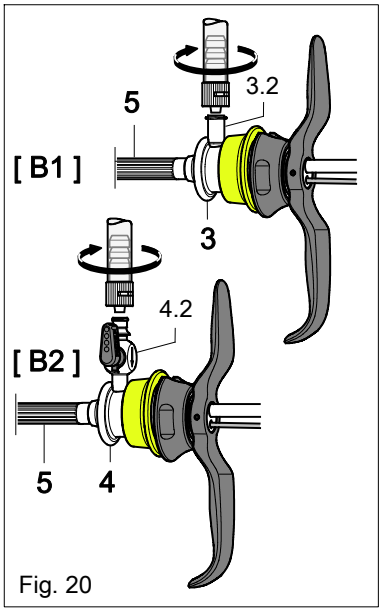


Fig. 20

Resectoscope sheaths (intermittent irrigation) B C

Resectoscope sheath (5) with rotatable irrigation adapter (3) [B1] / (4) [B2]

Fig. 20

◇ Connect the irrigation tube to the luer fitting (3.2) **[B1]** / luer stopcock (4.2) **[B2]**.

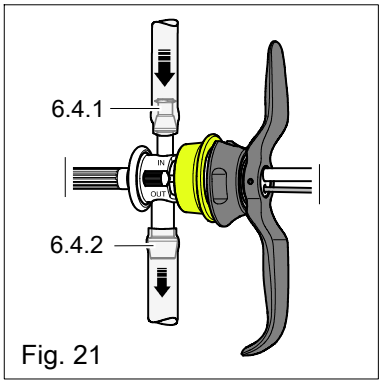


Fig. 21

Resectoscope sheaths with central stopcock C

Fig. 21

◇ Connect the irrigation and drain tubes to the luer fitting **"IN"** (6.4.1) and the **"OUT"** connector (6.4.2).

7.2.2 Atraumatic insertion of resectoscope sheath

⚠ *CAUTION!*
Do not insert the resectoscope sheath without obturator!
This may cause inadvertent tissue damage.
Insert the resectoscope sheath only atraumatically with the obturator in place.

◇ Insert the obturator into the resectoscope sheath and introduce into the urethra.
- ◗ Obturator (8): see section 7.1.5
- ◗ Dilation obturator (9) see section 7.1.6
- ◗ Viewing obturator (10): section 7.1.8
  Connect the fiber light cable to the PANOVIEW telescope (11) and a suitable light projector, switch on the light projector.

◇ Remove the obturator (8) (9) (10).

7.2.3 Connecting "Shark" resectoscope to system components

◇ Connect the fiber light cable to the PANOVIEW telescope (11) and to a suitable light projector, switch on the light projector.
◇ Connect the monopolar HF connection cable to the instrument and to the HF surgical device.
◇ Insert the working element (12) with the electrode (13) and the PANOVIEW telescope (11) into the resectoscope sheath already in situ: see section 7.1.11
◇ Switch on the irrigation fluid supply.
◇ Carry out a function check: see section 8.2

Resectoscope sheaths with central stopcock C

When reaching the bladder capacity:
◇ Stop the supply: move the stopcock plug (6.5) to the "0" position.
- ◗ The stopcock plug (6.5) engages in this position (locking position).

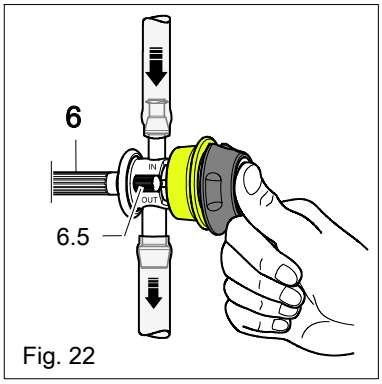


Fig. 22

Fig. 22

◇ Remove the working element (12).
◇ Lift the resectoscope sheath (6) proximally and close the opening with your thumb.
◇ Set the stopcock plug (6.5) to "OUT".
- ◗ The siphon effect empties the bladder and evacuates any tissue strips or concretions.

Resectoscope sheath with rotatable irrigation adapter B

◇ When using the two-way stopcock (883.01), it only serves as a drain, however no tissue strips etc. can be evacuated.

7.2.4 Irrigation fluid

⚠ *CAUTION!*
Irrigation fluid can be electrically conductive!
Depending on the application, a suitable low-conductivity irrigation fluid must be selected by the user.
Do not use saline (NaCl) solution for HF applications.

⚠ *CAUTION!*
Danger of elevated temperatures when working without irrigation fluid!
Injuries to the mucous membrane due to excessive temperatures endanger the patient.
Activate the electrode only while it is immersed in irrigation fluid and under continuous irrigation.

7.3 HF applications

⚠ *WARNING!*
Danger of injury if the HF instrument is not visible through the scope !
Inadvertent tissue damage as well as damage to the distal end of the endoscope and instrument parts are possible.
Use the HF instruments within the scope of their specifications (voltage strength, mode of operation).
Activate the HF instruments only after the part conducting HF current has become fully visible through the scope and contact is made with the intended area to be treated.

⚠ *WARNING!*
Explosion hazard if the electrode is activated in an air or gas bubble (e.g. roof of the bladder)!
This may cause injuries of the bladder or uterus wall.
Activate HF current only if:
- *the electrode is visible through the scope and is fully immersed in the irrigation fluid*
- *the desired tissue contact is made.*

☞ *NOTE!*
In order to remove the air bubbles generated during vaporization, we recommend using continuous-irrigation resectoscopes sheaths or suprapubic aspiration.

⚠ *CAUTION!*
Careful if HF voltage is too high!
Danger of injury resulting from damage to the electrode insulation!
Exceeding the maximum recurring peak voltage for the electrode in combination with HF surgical devices and / or selecting the wrong mode can destroy the insulation and cause leakage currents.
The patient, user or others may suffer tissue damage!
Use electrodes in conjunction with HF surgical devices only at a recurring peak voltage of max. 2 kV, even in forced or spray coagulation.

We recommend using the following power settings:
Single-use electrodes
- *Cutting mode:* *120 - 180 Watt*
  Coagulation mode: *maximum 100 Watt*

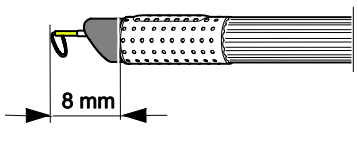


Fig. 23

⚠ *CAUTION!*

Danger of HF arcing during spray coagulation!

Insufficient distance between the parts conducting high-frequency current and other conductive parts can lead to unintentional tissue damage and damage to the instrument.

During activation, parts of HF instruments conducting high-frequency current must maintain a safe distance of at least 8 mm from the distal end of the endoscope / sheath (Fig. 23).

In the case of HF arcing, replace the electrode immediately, check the endoscope for damage and send it in for repair if necessary to avoid consequential damage.

⚠ *CAUTION!*

Careful with excessively high power settings in the area of the sphincter/cervix!

This may cause thermal damage and a dysfunction of the sphincter or cervix When the tissue turns brown or black or is carbonized this is an indication of excessive power.

Depending on the electrode power and mode, the depth effect (necrosis) is approx. 0.5 to 2 mm. Make sure that in particular in the proximity of the sphincter and cervix you use the utmost care and the smallest possible HF power.

⚠ *CAUTION!*

Do not activate HF current with installed stricture scalpel!

The stricture scalpel is not insulated and can cause injuries of the mucuous membrane when HF current is activated.

Before you work with the stricture scalpels, remove the HF connection cable from the HF connector of the working element.

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 instruments and accessories for damage, sharp edges, loose or missing parts and rough surfaces. Check the insulation with particular care.
◇ 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.
◗ Use new sterile electrodes.

8.1.1 Monopolar HF connection cable (14)

◇ Check the insulation and / or cable plugs for cracks and fractures and replace if necessary.

8.1.2 “Shark“ resectoscopes

⚠ *WARNING!*
Danger of injury!
Wrong handling, e.g. if dropped, impacted or damaged by similar mechanical loads can cause hair cracks and / or spalling of ceramic material in the distal area of the resectoscope sheath.
Injuries to the patient, user or third parties are possible.
Observe surface changes and ensure safe handling.
Do not use damaged resectoscope sheaths, return damaged sheaths for repair.

Fig. 24

◇ Check the ceramic insulation at the distal end of the resectoscope sheath for damage before every use.

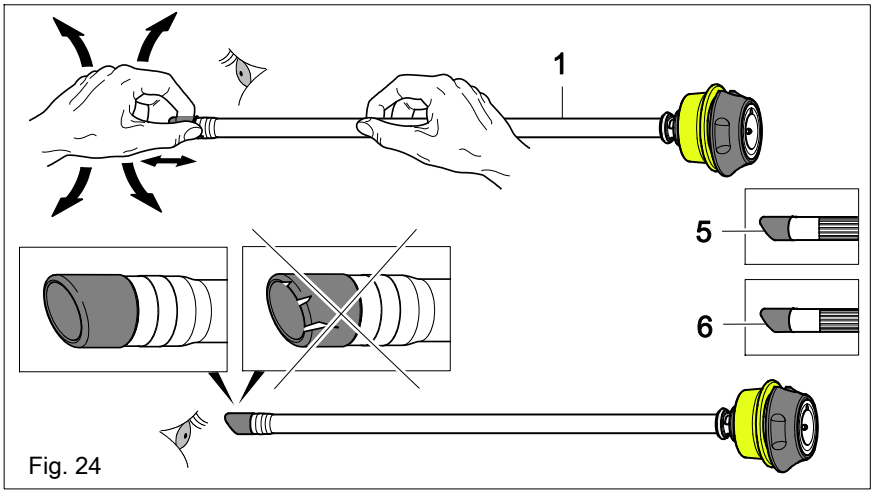


Fig. 24

◇ Replace damaged or brittle O-rings / caps (12.13).
◗ O-rings (1.3) (1.5)
◗ O-ring (7.5)
- “Shark“ resectoscope, rotatable [A] [B]
- “Shark“ resectoscope with central stopcock [C], non-rotatable

8.1.3 Electrodes

☞ *IMPORTANT!*

For sterile products:
***Sterility** is only guaranteed for undamaged and unopened packaging.*

- ◗ *Do not use the product if the sterile packaging is damaged or the use-by-date has been exceeded.*

◇ Disposable electrodes, sterile

- ◗ Check sterile packaging.

8.2 Function check

◇ Check the individual components for compatibility.

◇ 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 can only be locked with difficulty.

◇ Check rotatability of resectoscope [A] [B].

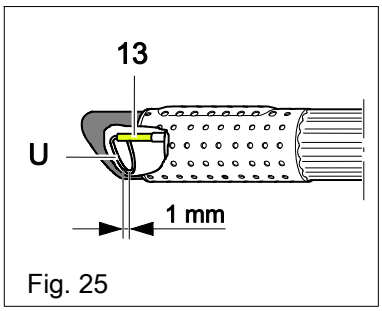


Fig. 25

Fig. 25

◇ Check if electrode (13) is locked in place:

- ◗ Insert the working element (12) into the resectoscope sheath (section 7.1.10) and fully retract the electrode (13) by means of working element (12). In this end position, the loop (U) of the electrode must be positioned approx. 1 mm behind the edge of the sheath.
  This is essential to ensure trouble-free tissue ablation.

◇ Check the function of the monopolar HF connection cable (14) in conjunction with the resectoscope and the HF surgical device.

◇ Check the irrigation or suction function.

◇ Check the entire system for leak-tightness and free passage (patency).

8.2.1 Irrigation (2.4), drain (2.6) and luer stopcock (4.2) with removable plug

◇ Check that the stopcock plug (2.4.2) is securely locked in the stopcock housing (2.4.1).

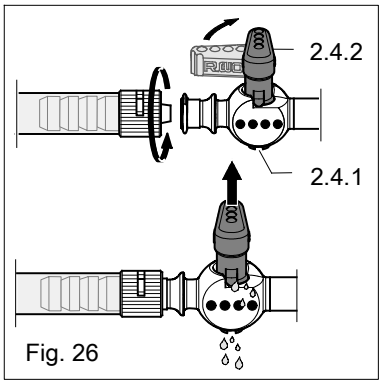


Fig. 26

Fig. 26

◇ Check the stopcocks (2.4) (2.6) (4.2) for leakage.

- ◗ Connect the supply tube, turn the stopcock plug (2.4.2) to its locked position.
- ◗ In case of leaking stopcocks: Replace the stopcock plug (2.4.2).

◇ Check that the stopcock plug (2.4.2) moves easily in the stopcock housing (2.4.1).

9 Reprocessing and maintenance

9.1 Dilation obturator (9)

☞ *IMPORTANT!*

Do not immerse the dilation obturator (9) in alcohol.
The flexible silicone tube of the obturator piston (9.1) can swell and become damaged.

9.2 Electrodes (13)

☞ *IMPORTANT!*

*Disposable electrodes with model/type numbers starting with **"4"** may only be used once.*
Discard disposable electrodes after use.

9.3 Disassembly before cleaning

◇ First disconnect the monopolar HF connection cable (14) from the resectoscope.
◇ Remove all connections between the resectoscope and the system components.
◇ Remove all parts used:
  ◗ Working element (12): see section 7.1.11
  ◗ Electrode (13): see section 7.1.10
  ◗ PANOVIEW telescope (11): see section 7.1.9
  ◗ Outer sheath (2) resectoscope [A]: see section 7.1.1

9.3.1 "Shark" resectoscope A B

◇ Rotatable irrigation adapter (3) (4) resectoscope [B]: see section 7.1.2

Inner sheath (1)

Fig. 27

◇ Remove only defective O-rings (1.3) (1.5) from the inner sheath (1) using the O-ring tool.

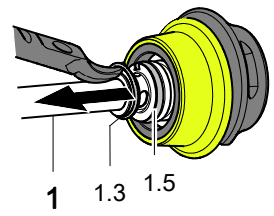


Fig. 27

9.3.2 "Shark" resectoscope with central stopcock C

Adapter (7)

Fig. 28

◇ Remove only a defective O-ring (7.5) using the O-ring tool.

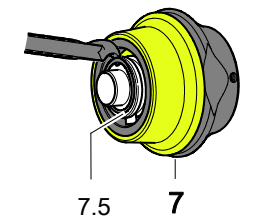


Fig. 28

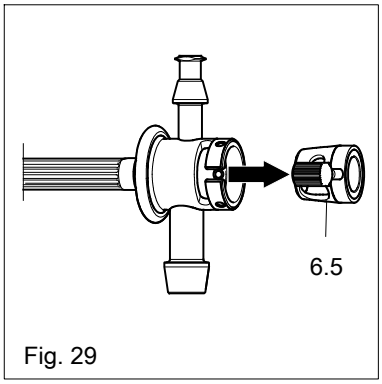


Fig. 29

Stopcock plug (6.5)

Fig. 29

◇ Position the stopcock plug (6.5) to the "0" position using the stopcock toggle and remove the stopcock plug (6.5).

9.3.3 Outer sheath (2) and rotatable irrigation adapter (4)

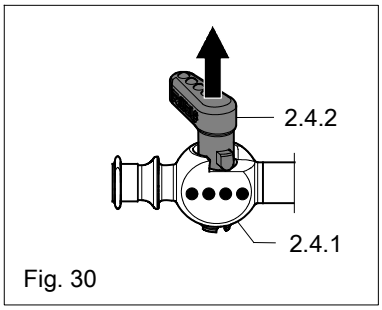


Fig. 30

Stopcock plug (2.4.2)

Fig. 30

Without disassembly tool

◇ Remove the stopcock plug (2.4.2).

◗ The stopcock plug (2.4.2) disengages from the stopcock housing (2.4.1).

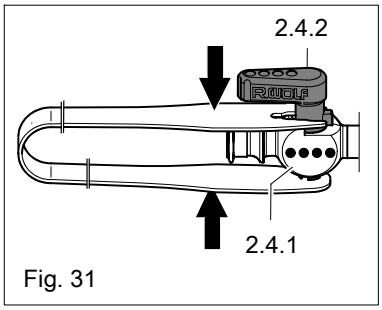


Fig. 31

Fig. 31

With disassembly tool

◇ Push the disassembly tool forward as far as it will go (see fig. 32) and push together.

◗ The stopcock plug (2.4.2) disengages from the stopcock housing (2.4.1).

◇ Remove the stopcock plug (2.4.2).

9.4 Illustrations on reprocessing

9.4.1 Manual cleaning

☞ *IMPORTANT!*

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

Inner sheath (1) and outer sheath (2), resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)

Fig. 32

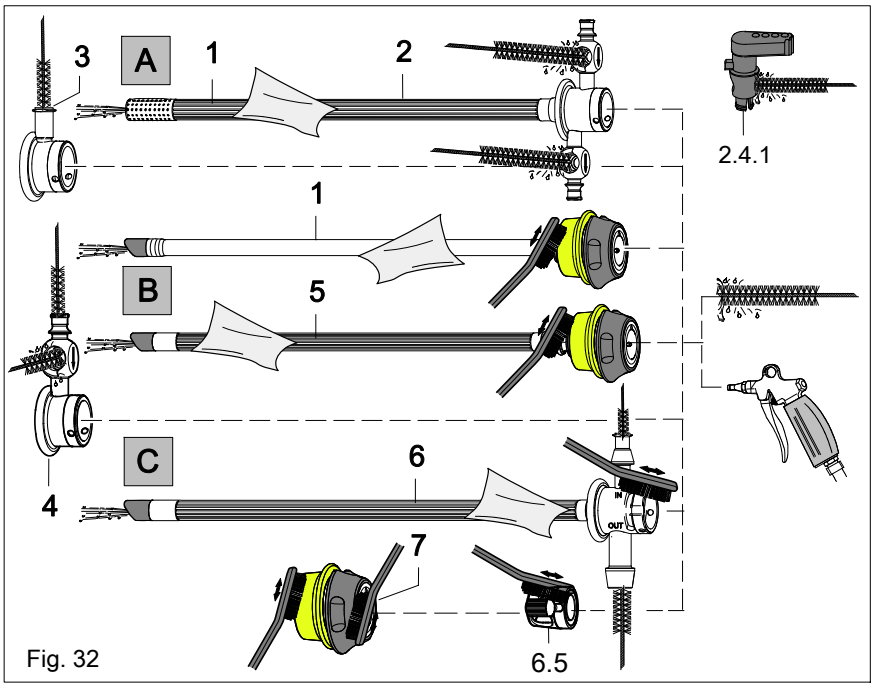


Fig. 32

Obturator (8) (9) (10)

Fig. 33

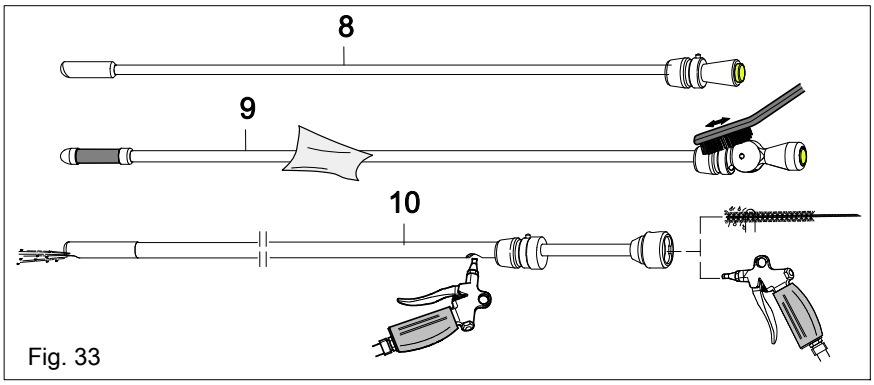


Fig. 33

Working element (12)

Fig. 34

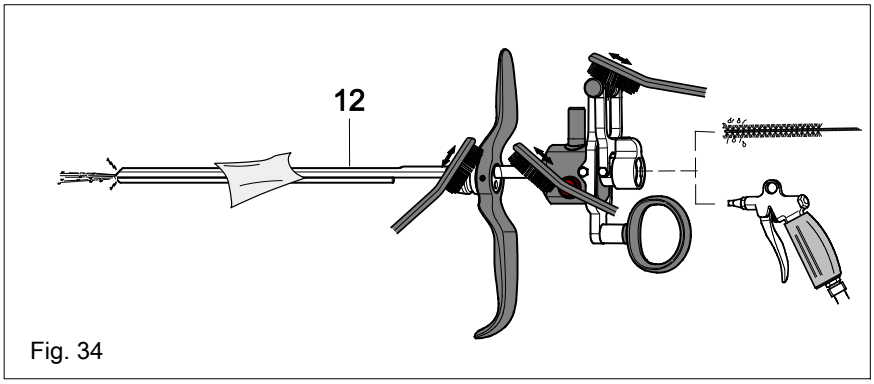


Fig. 34

Monopolar HF connection cable (14)

Fig. 35

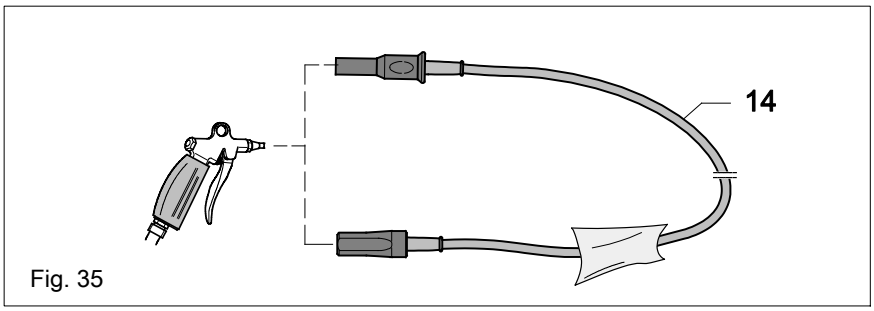


Fig. 35

9.4.2 Machine cleaning

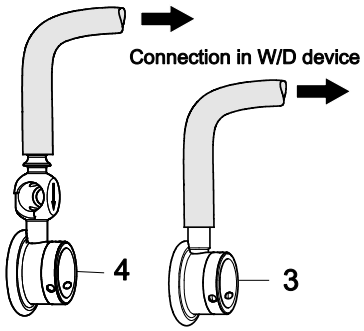


Fig. 36

Rotatable irrigation adapter (3) (4)

Fig. 36

Inner sheath (1) and outer sheath (2), resectoscope sheath (5), resectoscope sheath with central stopcock (6), viewing obturator (10)

☞ ***IMPORTANT!***

Close rinsing holes that are not used with dummy plugs (x).
When selecting the spray nozzles, follow the washer-disinfector manufacturer's instructions.

Fig. 37

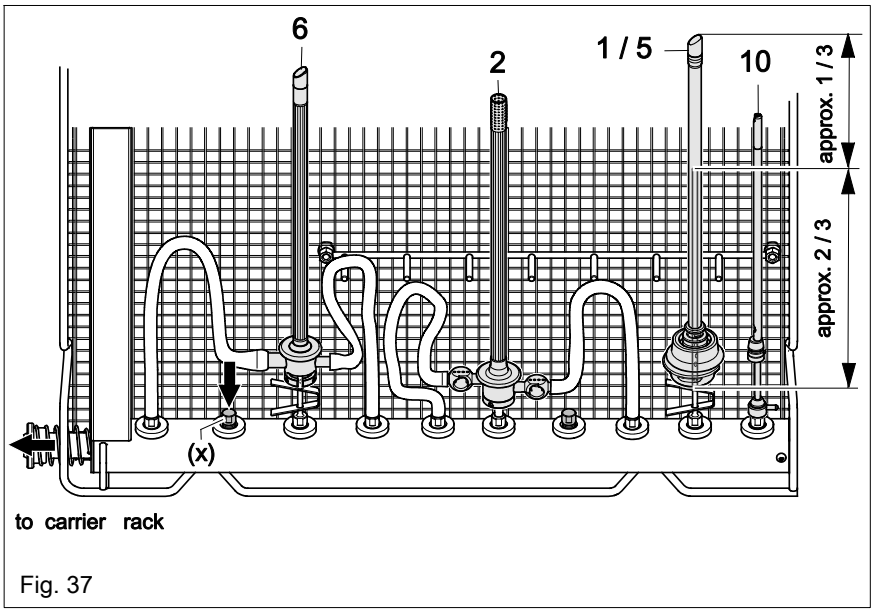


Fig. 37

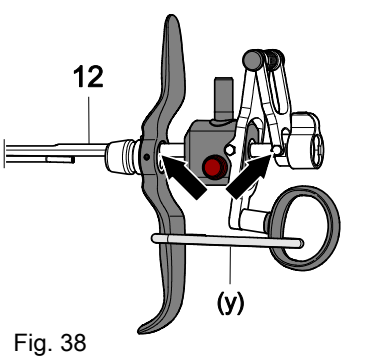


Fig. 38

Working element (12)

Fig. 38

To allow thorough cleaning in the area of the electrode lock, the electrode lock and supporting surfaces should not touch each other.
For this purpose RICHARD WOLF offers a cleaning clamp.

◇ Place a cleaning clip (y) into the handles.
➧ The electrode lock is in the cleaning position.

9.4.3 Care

Dilation obturator (9)

Fig. 39

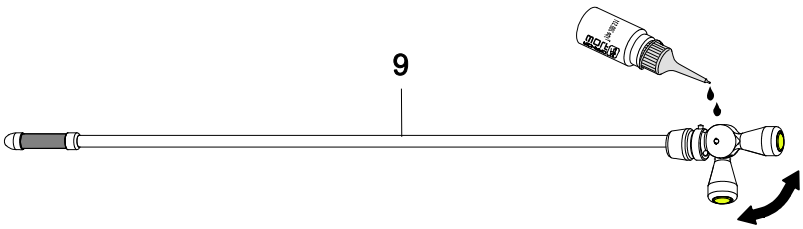


Fig. 39

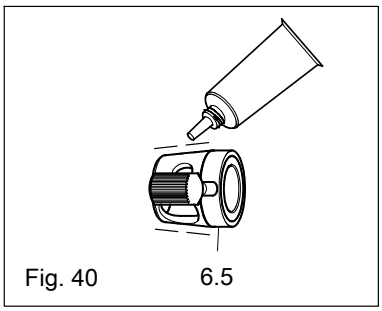


Fig. 40 6.5

Stopcock plug (6.5)

Fig. 40

9.5 Assembly before sterilization

9.5.1 Outer sheath (2) and rotatable irrigation adapter (4)

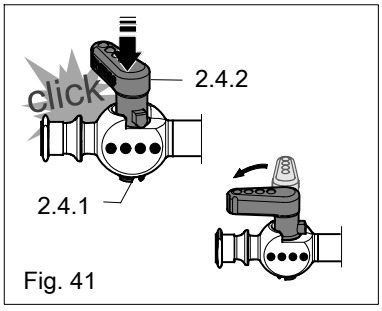


Fig. 41

Stopcock plug (2.4.2)

Fig. 41

◇ Insert the stopcock plug (2.4.2) into the stopcock housing (2.4.1).
➧ The stopcock plug (2.4.1) engages noticeably.
◇ Open the stopcock plug (2.4.1).

9.5.2 "Shark" resectoscope A B

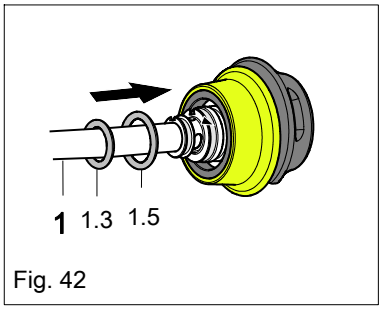


Fig. 42

Inner sheath (1)

Fig. 42

◇ If O-rings (1.3) (1.5) were removed, install new O-ring in the O-ring grooves on the inner sheaths (1).
◇ Assemble the rotatable irrigation adapter (3) (4) resectoscope [B]: see section 7.1.2

9.5.3 Resectoscope with central stopcock C

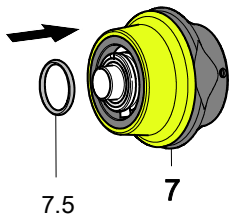


Fig. 43

Adapter (7)

Fig. 43

◇ If the O-ring (7.5) was removed, install a new O-ring in the O-ring groove of the adapter (7).

9.6 Reprocessing procedures

The following tables contain a description of the reprocessing procedures for the individual products validated by Richard Wolf.

☞ *IMPORTANT!*

- *When used as intended and when following the 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 gone through the entire reprocessing cycle.*
- *The user is obliged to make sure that the reprocessing process including the resources, materials and personnel is suited to yield the required results.*
- *Follow the national and international requirements on validation.*

Product:	Resectoscope sheaths [inner sheath (1) and outer sheath (2)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)	
Reprocessing guide:		
Preparation at the point of use:	Directly after use, remove any coarse soiling from the products. If there are more than 6 hours between use and reprocessing, rinse out the hollow spaces of the product with a 5 ml syringe filled with water. Do not use fixing agents or hot water (>40°C) as this will bake residues to the surfaces and may have a negative influence on the cleaning success. May use a pre-treat spray on the products prior to transport.	
Transport:	Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.	
Precleaning:	**Disassembly before cleaning: see section 9.3** Rinse out the products with hollow spaces for 20 seconds or with 5 pressure surges (2,5 - 4 bar) using a water cleaning gun.	
	Manual	**Machine**
Cleaning:	**See section 9.4.1, Fig. 32** 1. Rinse out narrow channels with a 5 ml syringe filled with enzymatic cleaning solution. 2. Immerse in an enzymatic cleaning solution for at least 5 minutes, then brush inside. 3. Brush outside for at least 5 seconds using a soft brush in order to remove any residues. 4. At the end, thoroughly rinse out the products for at least 20 seconds or in pulsed mode with 5 pressure surges (2,5 - 4 bar) using a water cleaning gun.	1. Before machine cleaning, preclean the products manually. ◗ **see section 9.4.1, Fig. 32** 2. Place the products (1) (2) (5) (6) onto the inserts (rinsing nozzles) of the MIC rack. 3. Connect the following products via the luer connector to the carrier rack of the W/D device: ◗ Irrigation stopcock (2.4) and drain stopcock (2.6) - outer sheath (2) ◗ Luer fitting (3.2) - rotatable irrigation adapter (3) ◗ Luer stopcock (4.2) - rotatable irrigation adapter (4) ◗ Luer fitting "IN" (6.4.1) and "OUT" connector (6.4.2) - resectoscope sheath with central stopcock (5) ◗ **see section 9.4.2, Fig. 36 and Fig. 37** 4. Place the stopcock plugs (2.4.2), (6.5), new O-rings (1.3) (1.5) and (7.5) in a small parts sieve. Program: ◗ >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*) with hot tap water (<40°C) ◗ Empty ◗ >2 min of intermediate rinsing with hot tap water (<40°C) ◗ Empty
Disinfection:	1. Dry the products to avoid diluting the disinfectant solution. 2. Immerse products in an approved disinfectant solution, allow to soak as specified by the manufacturer. ◗ Use a syringe to completely fill the channels with the solution. 3. Finally rinse out the products thoroughly for at least 20 seconds or, in pulsed mode, with 5 pressure surges (2,5 - 4 bar) using processed water**).	Carry out thermal machine disinfection following the national requirements regarding the A0 value (see DIN EN ISO 15883).
Drying:	Manual drying: Dry the external surfaces on the products with a lint-free disposable cloth or dry in a drying cabinet. Dry any hollow spaces with filtered compressed air.	Dry the products in the drying cycle of the washer-disinfector. If necessary, additional manual drying can be achieved using a lint-free disposable cloth or swab or alternatively in a drying cabinet. Dry hollow spaces with filtered compressed air.
Care:	**See section 9.4.3, Fig. 40** After manual / machine disinfection: 1. Sparingly grease the cone of the stopcock plug (6.5) with instrument grease.	
Function check, visual check, maintenance:	Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean. Sterilize the stopcock plug (6.5) and the resectoscope sheath (6) separately. ◗ **Carry out a visual check: see sections 8.1 and 8.1.2** ◗ **Assembly before sterilization see section 9.5**	

Product:	Resectoscope sheaths [inner sheath (1) and outer sheath (2)], resectoscope sheath (5), resectoscope sheath with central stopcock (6), rotatable irrigation adapter (3) (4), adapter (7)
Reprocessing guide:	
Packaging:	Package the products for sterilization as required by the standards.
Sterilization:	Steam sterilize the products in Pre-Vac cycle with the following parameters: ◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$) ◗ Evacuation: 3 x ◗ Drying time: 20 - 30 min ◗ Maximum sterilization temperature: 138°C **Other sterilization procedures: see section 9.7**
Storage:	Store the sterilized products 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%, in accordance with ANSI / AAMI ST79.
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 of the sterilizer specifications.

*) depending on the quality of the neutralization solution, add an acid based on citric acid.
**) use sterile water if manual disinfection is not followed by sterilization.

<table>
<tr><th>Product:</th><th colspan="2">Obturator (8), dilation obturator (9), viewing obturator (10)</th></tr>
<tr><th colspan="3">Reprocessing guide:</th></tr>
<tr><td>Preparation at the point of use:</td><td colspan="2">Directly after use, remove any coarse soiling from the products. If there are more than 6 hours between use and reprocessing, rinse out the hollow spaces of the product with a 5 ml syringe filled with water. Do not use fixing agents or hot water (>40°C) as this will bake residues to the surfaces and may have a negative influence on the cleaning success. May use a pre-treat spray on the products prior to transport.</td></tr>
<tr><td>Transport:</td><td colspan="2">Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.</td></tr>
<tr><td>Precleaning:</td><td colspan="2">Disassembly before cleaning: see section 9.3
Rinse out products with hollow spaces for 20 seconds or with 5 pressure surges (2,5 - 4 bar) using a cleaning gun.</td></tr>
<tr><td></td><td>Manual</td><td>Machine</td></tr>
<tr><td>Cleaning:</td><td>See section 9.4.1, Fig. 33
1. Rinse out narrow channels with a 5 ml syringe filled with enzymatic cleaning solution.
2. Immerse in an enzymatic cleaning solution for at least 5 minutes, then brush inside.
3. Brush outside for at least 5 seconds using a soft brush in order to remove any residues.
4. At the end, thoroughly rinse out the products for at least 20 seconds or in pulsed mode with 5 pressure surges (2,5 - 4 bar) using a cleaning gun.</td><td>1. Before machine cleaning, preclean the products manually.
◗ see section 9.4.1, Fig. 33
2. Place the obturator (8) and dilation obturator (9) in a sieve tray of the of the washer-disinfector.
3. Plug the viewing obturator (10) onto the insert (rinsing nozzle) of the MIC rack.
◗ see section 9.4.2, Fig. 37
Program:
◗ >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*) with hot tap water (<40°C)
◗ Empty
◗ >2 min of intermediate rinsing with hot tap water (<40°C)
◗ Empty</td></tr>
<tr><td>Disinfection:</td><td>1. Dry the products to avoid diluting the disinfectant solution.
2. Immerse products in an approved disinfectant solution, allow to soak as specified by the manufacturer.
3. Finally rinse the products thoroughly for at least 20 seconds using processed water**).</td><td>Carry out thermal machine disinfection following the national requirements regarding the A0 value (see DIN EN ISO 15883).</td></tr>
<tr><td>Drying:</td><td>Manual drying:
Dry the external surfaces on the products with a lint-free disposable cloth or dry in a drying cabinet. Dry any hollow spaces with filtered compressed air.</td><td>Dry the products in the drying cycle of the washer-disinfector.
If necessary, additional manual drying can be achieved using a lint-free disposable cloth or swab. Dry hollow spaces with filtered compressed air.</td></tr>
<tr><td>Care:</td><td colspan="2">See section 9.4.3, Fig. 39
After manual / machine disinfection:
1. Sparingly oil the inclinable handle (9.2) of the dilation obturator (9) by applying 1 - 2 drops of instrument oil. The other surfaces must be oil-free.
2. Remove any excess oil.</td></tr>
<tr><td>Function check, visual check, maintenance:</td><td colspan="2">Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
1. Check dilation on dilatable obturator piston (9.1): see section 7.1.6
◗ Carry out a visual check: see section 8.1</td></tr>
<tr><td>Packaging:</td><td colspan="2">Package the product for sterilization as required by the standards.</td></tr>
<tr><td>Sterilization:</td><td colspan="2">Steam sterilize the products in Pre-Vac cycle with the following parameters:
◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$)
◗ Evacuation: 3 x
◗ Drying time: 20 - 30 min
◗ Maximum sterilization temperature: 138°C
Other sterilization procedures: see section 9.7</td></tr>
<tr><td>Storage:</td><td colspan="2">Store the sterilized products 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%, in accordance with ANSI / AAMI ST79.</td></tr>
<tr><td>Additional instructions:</td><td colspan="2">It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.</td></tr>
</table>

*) depending on the quality of the neutralization solution, add an acid based on citric acid.
**) use sterile water if manual disinfection is not followed by sterilization.

<table>
<tr><th>Product:</th><th colspan="2">Working element (12)</th></tr>
<tr><th colspan="3">Reprocessing guide:</th></tr>
<tr><td>Preparation at the point of use:</td><td colspan="2">Directly after use, remove any coarse soiling from the product. Do not use fixing agents or hot water (>40°C) as this will bake residues to the surfaces and may have a negative influence on the cleaning success. May use a pre-treat spray on the product prior to transport.</td></tr>
<tr><td>Transport:</td><td colspan="2">Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.</td></tr>
<tr><td>Precleaning:</td><td colspan="2">Disassembly before cleaning: see section 9.3
No special requirements.</td></tr>
<tr><th></th><th>Manual</th><th>Machine</th></tr>
<tr><td>Cleaning:</td><td>See section 9.4.1, Fig. 34
1. Rinse out the locking cone (receptacle) (Z) with a 5 ml syringe filled with enzymatic cleaning solution.
2. Immerse in an enzymatic cleaning solution for at least 5 minutes, then brush inside.
3. Brush outside of working element (12) in particular in the area of the lock body (12.4) and on the locking cone (receptacle) (12.15) with a soft brush for at least 5 seconds to remove any residues.
4. At the end, rinse the working element (12) for at least 20 seconds.</td><td>1. Before machine cleaning, preclean the product (12) manually.
◗ see section 9.4.1, Fig. 34
2. Cleaning clamp (y) to the handles of the working element (12).
◗ see section 9.4.2, Fig. 38
Program:
◗ >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*) with hot tap water (<40°C)
◗ Empty
◗ >2 min of intermediate rinsing with hot tap water (<40°C)
◗ Empty</td></tr>
<tr><td>Disinfection:</td><td>1. Dry the products to avoid diluting the disinfectant solution.
2. Immerse products in an approved disinfectant solution, allow to soak as specified by the manufacturer.
3. Finally rinse the products thoroughly for at least 20 seconds using processed water**).</td><td rowspan="2">Carry out thermal machine disinfection following the national requirements regarding the A0 value (see DIN EN ISO 15883).

Dry the products in the drying cycle of the washer-disinfector.
If necessary, additional manual drying can be achieved using a lint-free disposable cloth or swab or alternatively in a drying cabinet. Dry hollow spaces with filtered compressed air.</td></tr>
<tr><td>Drying:</td><td>Manual drying:
Dry the external surfaces with a lint-free disposable cloth or dry in a drying cabinet. Dry any hollow spaces with filtered compressed air.</td></tr>
<tr><td>Function check, visual check, maintenance:</td><td colspan="2">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</td></tr>
<tr><td>Packaging:</td><td colspan="2">Package the product for sterilization as required by the standards.</td></tr>
<tr><td>Sterilization:</td><td colspan="2">Steam sterilize the products in Pre-Vac cycle with the following parameters:
◗ Temperature exposure time: 4 min at 132°C $^{+4°C}$ (270°F $^{+7°F}$)
◗ Evacuation: 3 x
◗ Drying time: 20 - 30 min
◗ Maximum sterilization temperature: 138°C
Other sterilization procedures: see section 9.7</td></tr>
<tr><td>Storage:</td><td colspan="2">Store the sterilized products 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%, in accordance with ANSI / AAMI ST79.</td></tr>
<tr><td>Additional instructions:</td><td colspan="2">It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.</td></tr>
</table>

*) depending on the quality of the neutralization solution, add an acid based on citric acid.
**) use sterile water if manual disinfection is not followed by sterilization.

<table>
<tr><th>Product:</th><th colspan="2">Monopolar HF connection cable (14)</th></tr>
<tr><th colspan="3">Reprocessing guide:</th></tr>
<tr><td>Preparation at the point of use:</td><td colspan="2">Directly after use, remove any coarse soiling from the monopolar HF connection cable (14). Do not use fixing agents or hot water (>40°C) as this will bake residues to the surfaces and may have a negative influence on the cleaning success. May use a pre-treat spray on the product prior to transport.</td></tr>
<tr><td>Transport:</td><td colspan="2">Safe storage in a closed container and transport of the products to the reprocessing room in order to avoid damage to the products and contamination of the environment.</td></tr>
<tr><td>Precleaning:</td><td colspan="2">Do not clean the monopolar HF connection cable (14) in an ultrasonic bath!
No special requirements.</td></tr>
<tr><th></th><th>Manual</th><th>Machine</th></tr>
<tr><td>Cleaning:</td><td>See section 9.4.1, Fig. 35
1. Immerse in an enzymatic cleaning solution for at least 5 minutes.
2. Clean with a soft lint-free disposable cloth to remove any residues.
3. At the end, rinse the monopolar HF connection cable (14) for at least 20 seconds.</td><td>Machine reprocessing up to max. 95°C (203°F)
Make sure that no other objects / products are placed on the monopolar HF connection cable (14) or touch it.
Program:
◗ >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*) with hot tap water (<40°C)
◗ Empty
◗ >2 min of intermediate rinsing with hot tap water (<40°C)
◗ Empty</td></tr>
<tr><td>Disinfection:</td><td>1. Dry the monopolar HF connection cable (14) to avoid diluting the disinfectant solution.
2. Immerse the monopolar HF connection cable (14) in an approved disinfectant solution, allow to soak as specified by the manufacturer.
3. Finally rinse the monopolar HF connection cable (14) for at least 20 seconds using processed water**).</td><td>Carry out thermal machine disinfection following the national requirements regarding the A0 value (see DIN EN ISO 15883).</td></tr>
<tr><td>Drying:</td><td>Manual drying:
Dry the external surfaces on the monopolar HF connection cable (14) using a lint-free disposable cloth or dry in a drying cabinet. Dry the plugs with filtered compressed air.</td><td>Dry the monopolar HF connection cable (14) in the drying cycle of the washer-disinfector.
If necessary, additional manual drying can be achieved using a lint-free disposable cloth or swab or alternatively in a drying cabinet. Dry hollow spaces with filtered compressed air.</td></tr>
<tr><td>Function check, visual check, maintenance:</td><td colspan="2">Check visually for cleanliness. If necessary, repeat the reprocessing procedure until the product is visually clean.
◗ Carry out a visual check: see sections 8.1 and 8.1.1</td></tr>
<tr><td>Packaging:</td><td colspan="2">Package the monopolar HF connection cable (14) for sterilization as required by the standards.</td></tr>
<tr><td>Sterilization:</td><td colspan="2">Steam sterilize the products in Pre-Vac cycle with the following parameters:
◗ Temperature exposure time: 4 min at 132°C +4°C (270°F +7°F)
◗ Evacuation: 3 x
◗ Drying time: 20 - 30 min
◗ Maximum sterilization temperature: 138°C
Other sterilization procedures: see section 9.7</td></tr>
<tr><td>Storage:</td><td colspan="2">Store the sterilized products 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%, in accordance with ANSI / AAMI ST79.</td></tr>
<tr><td>Additional instructions:</td><td colspan="2">It is the responsibility of the user to ensure that the reprocessing equipment has been installed, calibrated and validated according to the manufacturer of the sterilizer specifications.</td></tr>
</table>

*) depending on the quality of the neutralization solution, add an acid based on citric acid.
**) use sterile water if manual disinfection is not followed by sterilization.

9.7 Alternate Sterilization Methods

◇ For possible alternate sterilization methods, refer to our website, www.richardwolfusa.com under „Reprocessing & Sterilization“ for lists of Richard Wolf instruments that are approved for various reprocessing methods.

10 Technical data and order data

For this, see brochure BB-D366, System overview of "Shark“ resectoscopes.

10.1 Electrodes for resectoscopes 8675xxx / 86763xxxx, PANOVIEW telescope 4 mm, 12° / 30°

10.1.1 Single-use electrodes, sterile

Item	Electrode	Fork	Continuous-irrigation sheath	without	with		Electrode shape	Loop	Package Unit
				Guide nose					
				-	1st step	2nd step			
		Color	in Fr.					in [mm]	
D	46782225	green	22 / 24	■	□	□	Cutting loop	0.25	10 / box
	46782235	green	22 / 24	■	□	□	Cutting loop	0.35	
	46782425	yellow	24 / 26	□	■	□	Cutting loop	0.25	
	46782435	yellow	24 / 26	□	■	□	Cutting loop	0.35	
	46782635	black	26	□	□	■	Cutting loop	0.35	
E1	46782201	green	22 / 24 24 / 26	■	□	□	Roller	□	5 / box
E2	46782202	green	22 / 24 24 / 26	■	□	□	Roller	□	
E3	46782203	green	22 / 24 24 / 26	■	□	□	Button	□	
	46782603	black	26	□	□	■	Button	□	
G1	46782204	green	22 / 24 24 / 26	■	□	□	Knife	□	
	46782604	black	26	□	□	■	Knife	□	
F	46782205	green	22 / 24 24 / 26	■	□	□	Hook	□	
	46782605	black	26	□	□	■	Hook	□	
D	46782480	yellow	24 /26	□	■	□	Cutting loop	0.8	

On the cutting electrodes the color of the fork primarily indicates to what resectoscope sheath they belong (Fr. size).

■ = yes □ = no

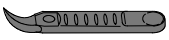
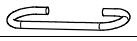
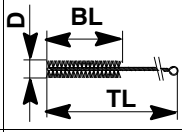
10.2 Electrodes for resectoscopes 8675xxx / 86763xxxx, PANOVIEW telescope 4 mm, 0°

10.2.1 Single-use electrodes, sterile

Item	Electrode	Fork	Continuous-irrigation sheath	Electrode shape	Loop	Package Unit
		Color	in Fr.		in [mm]	
D	46792235	green	22 / 24	Cutting loop	0.35	5 / box
	46792435	yellow	24 / 26	Cutting loop	0.35	
	46792635	black	26	Cutting loop	0.35	
E1	46792201	green	22 / 24 24 / 26	Roller	☐	
G2	46792204	none	22 / 24 24 / 26	Knife	☐	
F	46792205	none	22 / 24 24 / 26	Hook	☐	

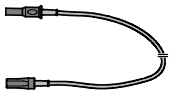
11 Spare parts and accessories

11.1 "Shark" Resectoscopes

Item	Illustration	Product no.	Designation	"Shark" Resectoscope		
				A	B	C
				rotatable		non-rotatable
1.3		15364395	**O-Ring 7,65 X 1,78-VMQ-70 coated**	■	■	☐
1.5 7.5		15364396	**O-Ring 9,25 X 1,78-VMQ-70 coated**	■	■	☐
2.4.2		896.0003	**Stopcock plug, complete** Passage 4.2 mm; Identification: 4 pegs Packaging unit = 5 / pkg.	■	■	☐
-		38310.0001	**Disassembly tool**	■	■	☐
11.13		8874	**Rubber cap** for sealing off the electrode clamping mechanism on the working channel, color: red Packaging unit = 5 / pkg.	■	■	■
-		15 106.230	**O-ring tool**	■	■	■
-		200.532	**Oil drip bottle 27.5 ml**	■	■	■
-		20012	**Instrument grease** 10 ml tube, steam-sterilizable	☐	☐	■
(y)		15242024	**Cleaning clamp for working elements**	■	■	■
-		6.09	**Cleaning brush** Total length TL = 405 mm; brush dia. ∅ = 9 mm; Brush length BL = 80 mm	■	■	■
-		86.90	**Cleaning brush** Steam-sterilizable universal brush	■	■	■

■ = yes ☐ = no

11.2 Monopolar HF connection cable (14)

Item	Illustration	Product no.	Designation	Cable length	only compatible with HF surgical device
14		815.132	Monopolar HF connection cable	3 m	ERBE T-Series
		815.152	Monopolar HF connection cable	5 m	
		815.033	Monopolar HF connection cable	3 m	-BOVIE- -VALLEYLAB- -ERBE INT.-
		815.053	Monopolar HF connection cable	5 m	

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

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

Disposible items, sterile products	Follow instructions on package !

☞ ***IMPORTANT!***

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

☞ ***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 comply with the country-specific laws and regulations.

➧ Further information is available from the manufacturer on request.

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.