Instructions

Flexible Fiberscopes

7305.xxx/7321.xxx/7325.xxx/7330.xxx
Important general instructions for use

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

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

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

Subject to technical changes!

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

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

Safety instructions and levels of danger

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Level of danger</th>
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<tbody>
<tr>
<td>⚠️</td>
<td>WARNING! Failure to observe can result in death or serious injury.</td>
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<td>⚠️</td>
<td>CAUTION! Failure to observe can result in slight injury or damage to the product.</td>
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<tr>
<td>⚠️</td>
<td>IMPORTANT! Failure to observe can result in damage to the product or surrounding.</td>
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<td>⚠️</td>
<td>NOTE! Tips for optimum use and other useful information.</td>
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1 Intended use

The flexible fiberscopes are used to visualize body cavities and hollow organs via natural or surgically created passages.

2 Indications and field of use

For examination, diagnosis and/or therapy in conjunction with endoscopic accessories and auxiliary instruments used through the working channel of this instrument.

2.1 Field of use 7305.xxx / 7325.xxx / 7330.xxx

This instrument is used in the medical disciplines of urology, surgery, gynecology and ENT by adequately trained and qualified medical personnel. Applications on the heart and the central nervous and circulatory systems are excluded.

IMPORTANT!
The product dimensions must match the anatomic conditions, i.e. the correct flexible fiberscope must be selected for the relevant medical discipline.

2.2 Field of use 7321.164

This instrument is used in the medical disciplines of urology, surgery, gynecology ENT and neurosurgery by adequately trained and qualified medical personnel.

3 Contraindications

Contraindications directly related to the product are presently unknown. On the basis of the patient’s general condition the physician/surgeon in charge must decide whether the planned use is possible or not. For further information see the latest medical literature.

3.1 Contraindications in neurosurgery

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

On the basis of the patient’s general condition the physician/surgeon in charge must decide whether the planned use is possible or not. Follow the regulations and laws valid in your country. For further information see the latest medical literature. Contraindications directly related to the product are presently unknown.

4 Combinations

The flexible fiberscopes are used in connection with light sources and flexible light cables, video cameras or reflex cameras and objective lenses, suction and irrigation devices, as well as endoscopic accessories (forceps, HF instruments, sheaths, laser fibers, etc.)

CAUTION!
Caution if products are incorrectly combined!
May result in injury to the patient, user or others and damage may result to the product. Different products should only be used in combination if their intended uses and relevant technical data (working length, diameter, peak voltage, etc.) are the same. Follow the instruction manuals of the products used in conjunction with this product.

IMPORTANT!
If the fiberscopes are used as ureterorenoscopes or in choledochus revisions they must be placed via a guide wire.
The cold-light connector (4) can be unscrewed and replaced by suitable adapters to connect flexible light cables of other manufacturers (Fig. 1). For order data please refer to the latest catalog sheet.

Luer connector (15) 7305.781 (Fig. 2). For the use of disposable stopcocks.

Insertion stopcock (14) 8954.765 with rubber cap (Fig. 3). For the introduction of laser fibers.

Adapter (16) 7305.782 with rubber cap (Fig. 4). comprising:
- Insertion stopcock and two irrigation stopcocks.

Objective lenses with C-mount or RW-mount thread for working via the monitor (Fig. 5). For order data please refer to the latest catalog sheet.
5.1 Legend and identification

<table>
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<tr>
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<tr>
<td>1</td>
<td>Objective lens</td>
<td>14</td>
<td>Insertion stopcock</td>
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<tr>
<td>2</td>
<td>Light exit</td>
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<td>Luer connector</td>
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<td>3</td>
<td>Instrument tip, deflectable</td>
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<td>Adapter</td>
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<td>Cold-light connector</td>
<td>16.1</td>
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<td>9</td>
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<td>Connector for leakage test and</td>
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<td>Identification in conformity with Medical Devices Directive 93/42/EEC only valid if the product and/or packaging is marked with this symbol. Products of category IIa and above, as well as sterile products or products with measuring function of category I, are additionally marked with the code number of the notified body (0124).</td>
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6 Use

⚠️ CAUTION!
The products have only limited strength! Exerting excessive force will cause damage, impair the function and therefore endanger the patient. Immediately before and after each use, check the products for damage, loose parts and completeness. Ensure that no missing instrument parts remain in the patient. Do not use products which are damaged, incomplete or have loose parts.

⚠️ IMPORTANT!
Fiberscope which have only been disinfected, must be disinfected again before the first examination of the day.

6.1 Preparation

- Carry out a check: see sections 7 and 7.1
- Tighten the cold-light connector (4).

6.1.1 Attaching insertion stopcock (14)

Fig. 7
- Provide insertion stopcock (14) with rubber cap (17).
- Introduce the insertion stopcock (14) into the threaded connection (6) in such a way that nose (b) engages in guide groove (a).
- Tighten the locking collar (c) as indicated by the arrow.

6.1.2 Attaching adapter (16)

Fig. 8
- Check assembly: see section 8.4.1
- Place the rubber cap (17) onto the adapter (16).
6.1.3 Attaching Luer connector (15) or adapter (16)

- Adapter (16) with rubber cap (17)
- Push the sealing cap (f) as far as it will go, as indicated by the arrow (Fig. 1).
- Insert the Luer connector (11) in the slot of the sealing cap, Fig. 2, and let go of sealing cap (f).
- The sealing cap (f) must return to its initial position (Fig. 3).

Connect the flexible light cable (e) to the instrument and to a light source.

**IMPORTANT!**
Maximum light output with minimal heating of the connection is achieved with a flexible light cable having the same effective diameter as the flexible fiberscope. This means:
- 1.6 mm dia. for Flexible Fiberscopes 7321.xxx / 7325.xxx / 7330.xxx
- 2.5 mm dia. for Flexible Fiberscope 7305.xxx

- Carry out the function check: see section 7.2

6.2 Additional notes and instructions for use

**CAUTION!**
The products have only limited strength!
Exerting excessive force or applying high mechanical loads can cause damage (e.g. breaking of cables / fracture of light cable) and impair the function.
Do not kink or excessively bend the flexible instrument sheath (12), do not bend to a radius of less than 100 mm (10 cm) (Fig. 10).

**CAUTION!**
Be careful if movement of the instrument tip (3) is restricted (e.g. through lack of space)!
The control mechanism can be damaged.
Do not use force when moving the control lever (9) if the instrument tip (3) is blocked. Move the instrument tip (3) to a position allowing control without applying force.
CAUTION!
Danger of injury when removing the fiberscope with the instrument tip (3) angled and locked in position. Inadvertent tissue damage as well as damage to the fiberscope is possible. Deactivate the locking function (control lever 9), straighten the instrument tip (3) (0° position) and remove the fiberscope.

6.2.1 Locking the instrument tip (3)

Fig. 11
The control lever (9) serves to lock the instrument tip (3) in any angled position required.

- Locking the instrument tip (3):
  Push the control lever (9) in direction of arrow as far as it will go.

- The locked instrument tip (3) is unlocked (released) by returning the control lever to its initial position.

6.2.2 Light

IMPORTANT!
Use only products with Type BF applied parts in conjunction with this flexible fiberscope.

WARNING!
Heat may be generated due to high light energy!
Danger of unintentional tissue damage
- due to insufficient distance between the light exit area and the tissue
- due to soiling/contamination in the light exit area
- if high-performance projectors are used.
Do not touch the light exit area and avoid direct contact with the tissue. Remove any soiling.

WARNING!
Fire hazard!
Do not place the light exit area against heat-sensitive, flammable surfaces (e.g. dark drapes, etc.) as this may lead to inadmissibly high temperatures or ignite the material.
Lay down the fiberscope at a safe place.
Switch off the light source if the fiberscope is not used for a period of time.

CAUTION!
Danger of burns!
As a result of the high level of light energy at the cold-light connector, the connector is extremely hot when it is disconnected from the light source. Burns may result from unintentional contact with the connector.
Do not touch the cold-light connector before it has cooled down.

6.2.3 Current

WARNING!
Danger of electrical shock!
Patient leakage currents can add up if endoscopes are combined with electrically powered endoscopic accessories. Make sure that the combinations do not exceed the permissible patient leakage currents.
6.2.4 Image quality

**CAUTION!**
*Increased danger potential if image is blurred!*
*Patient may be injured.*
*Stop operation for safety reasons if image is blurred.*
*Check image quality of fiberscope before use (see section 7.2.2).*

6.2.5 Irrigation fluid

**CAUTION!**
*Irrigation fluids can be electrically conductive!*
*The user must choose a low-conductivity irrigation fluid suitable for the application.*
*Do not use NaCl (saline) for HF applications.*

**CAUTION!**
*DANGER OF INJURIES TO THE MUCOUS MEMBRANE!*
*If suction is activated for some time while the instrument tip is in direct contact with the mucous membrane, bleeding of the mucous membrane may result.*
*Carry out suction under visual control and at short intervals.*

6.3 HF application

Make sure you observe the “Instructions and notes on HF applications”, order no.: GA-S 002 as well as the HF device manufacturer’s instructions.

**WARNING!**
*DANGER OF INJURY IF THE HF INSTRUMENT IS NOT VISIBLE THROUGH THE SCOPE!*
*The fiberscope is not equipped with additional insulation for HF applications.*
*Inadvertent tissue damage as well as damage to the distal end of the fiberscope and the instrument parts are possible.*
*HF instruments should therefore be used only within the scope of their specifications as to electric strengths and mode of operation.*
*Activate HF instruments only if the live high-frequency part is fully visible through the fiberscope and in contact with the area to be treated (Fig. 12).*

**WARNING!**
*HF arcing!*
*DANGER OF INJURY DUE TO INCORRECT HF APPLICATION AND INSUFFICIENT DISTANCE BETWEEN LIVE HF INSTRUMENTS AND OTHER CONDUCTIVE PARTS.*
*Live high-frequency parts of HF instruments must be kept at a safe distance of at least 10 mm from the distal end of the fiberscope when they are activated (Fig. 13).*
WARNING!
Danger of burns!
Unintentional oxygen supply during HF and laser applications can cause burns to the patient, user or others.
Avoid any oxygen supply during HF and laser applications.

CAUTION!
Take care when selecting the HF output power. Do not use excessive HF output power!
The patient may be injured and the product may become damaged.
The power must be set in accordance with the experience and/or training of the surgeon with regard to the respective indication.
Any use in conjunction with the SPRAY coagulation mode is not permissible.

6.4 Laser application

When using lasers, make sure you observe the laser device manufacturer’s instructions as well as the general instructions on the use of lasers.
Wear the required personal protection gear.

CAUTION!
Do not work outside the scope’s field of view!
Inadvertent tissue damage as well as damage to the distal end of the fiberscope and instrument parts can occur.
Activate the laser only after
- the tip of the laser fiber has become fully visible through the fiberscope
and
- the area to be treated makes contact by means of the pilot beam

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 at a safe distance.

CAUTION!
There is the risk of destroying the working channel with the sharp distal end of the fiber!
The stronger (stiffer) the laser fiber, the higher the risk that the sharp distal end of the laser fiber will perforate the working channel.
It is therefore necessary to introduce the laser fiber carefully into the working channel (13) and only with a straight instrument tip (3) (0° position).

CAUTION!
Danger of destroying the instrument by a fracture of the laser fiber!
When the instrument tip is angled (small bending radius) the danger of fracturing the laser fiber increases as the fiber diameter increases. If the laser fiber breaks within the instrument channel while the laser energy is active, the instrument will be destroyed immediately.
Switch off laser energy immediately.
We therefore recommend using only highly flexible laser fibers with a diameter of 200μm.
The use of laser fibers with a diameter exceeding 400μm is not permissible.

CAUTION!
Danger of eye injury when using lasers without filter attachment!
Use a suitable filter attachment on the fiberscope eyepiece.
6.5 Auxiliary instruments and endoscopic accessories

⚠️ CAUTION!
In order to avoid damaging the working channel,
- do not forcefully introduce auxiliary instruments into the working channel or withdraw instruments from the working channel (Fig. 14a)
- Introduce auxiliary instruments into the working channel or withdraw instruments from the working channel only when the instrument tip is straight (Fig. 14b).

Angle the fiberscope only after the auxiliary instrument is fully visible through the scope. When the fiberscope tip is at an angle, the auxiliary instrument may be further extended, but retracted only to just before the fiberscope tip (Fig. 14c).
7 Checks

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

7.1 Visual check
- Check the flexible fiberscopes and the accessories, in particular their distal areas, for damage, sharp edges, loose or missing parts and rough surfaces.
- Any lettering, labeling or identification necessary for the safe intended use must be legible.
  - Missing or illegible lettering, labeling or identification which may lead to wrong handling and reprocessing must be reinstated.
- Check for correct connection of endoscopic accessories.
- Check that the relevant technical data (diameter, working length, etc.) of endoscopic accessories and the flexible fiberscope are the same.
- Check sealing caps and O-rings for damage and replace.

7.2 Functional check
- Check that the connections are securely locked.

7.2.1 Adapter (16)
- Check irrigation and drainage flow of the stopcocks (16.1).
- Check that the stopcock plug (16.1.1) snaps into the stopcock housing (16.1.2).

Fig. 15
- Check the stopcocks (16.1) for leak-tightness.
  - Turn the stopcock plug (16.1.1) to the locked position.
  - If stopcocks leak, replace stopcock plug (16.1.1).
- Check the stopcock plug (16.1.1) for easy operation in housing (16.1.2).
7.2.2 Fiberscope

- Make sure that all parts are securely connected.
- Check angling, locking and unlocking of the instrument tip (3).
  - Angling (deflection): see section 9.1
  - Locking and unlocking: see section 6.2.1
- Check the working channel (13) for patency (free passage).
- Check image quality and light output in conjunction with the system components.
- Check the glass surfaces for deposits.
  - Deposits on the glass surfaces can cause a spotted or blurred field of view and can impair light transmission considerably.
  - Clean the glass surfaces with a swab, soaked with alcohol (wooden swab carrier, not metal or plastic), remove hard-to-remove deposits with instrument cleaner (Fig. 16).

![Fig. 16](image)

- Check the light output without the system components.
- Hold the distal end of the fiberscope towards a light source.
  - Broken fibers will appear as black dots on the cold-light connector. If approx. 30% of the fibers are broken the light output is no longer sufficient (Fig. 17).

![Fig. 17](image)
7.2.3 Manual leakage test

**IMPORTANT!**
Carry out a leakage test immediately after each use and always before reprocessing.

**Fig. 18**
- Connect the leakage tester (163.903) to the connector for leakage test and pressure equalization (10).
- Place the locking collar (a) on the connector for leakage test and pressure equalization (10) as far as it will go and secure by turning clockwise.
- Close the knurled screw (b).
- Use the rubber bulb (air pump) to inflate the fiberscope until the needle is in the green range (100 - 200 mmHg).
  - An initial pressure drop is caused by the resilience of the elastic tubing.
  - The fiberscope leaks if the pressure drops within 30 seconds.
  - In the latter case return the fiberscope to RICHARD WOLF for repair.
  - If the pressure reading remains constant, the fiberscope is leak-proof.
- The pressure is released by opening the knurled screw (b).

**IMPORTANT!**
After opening the knurled screw, wait at least 20 seconds before you remove the test unit. This is necessary to ensure complete pressure equalization.
8 Reprocessing and maintenance

⚠️ WARNING!
Creutzfeldt-Jakob Disease!
If the patient is suspected of having Creutzfeldt-Jakob Disease (CJD) or if a variant of Creutzfeldt-Jakob Disease (vCJD) has 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 regulations and guidelines.

8.1 Disassembly before cleaning

- Disconnect all connections between the fiberscope and the system components.
- Unscrew the cold-light connector (4).

8.1.1 Insertion stopcock (14), Luer connector (15), Adapter (16)

- Immediately after use, remove the insertion stopcock (14) / luer connector (15) / adapter (16).
- For the disassembly, proceed in reverse order as described under section 6.1.1 and 6.1.3.

Insertion stopcock (14), adapter (16)

Fig. 19

- Removing the stopcock plug (16.1.1) - without disassembly tool.
  - The stopcock plug (16.1.1) snaps out of the housing (16.1.2).

Fig. 20

- Removing the stopcock plug (16.1.1) - with disassembly tool (see section 10).
  - Push the disassembly tool forward as far as it will go - as shown in fig. 20 - and push together.
  - The stopcock plug (16.1.1) disengages from the stopcock housing (16.1.2).
- Remove the stopcock plug (16.1.1).
8.2 Cleaning

8.2.1 Manual cleaning

**IMPORTANT!**
Do not clean flexible fiberscopes in ultrasonic baths!

**IMPORTANT!**
Use only cleaners whose efficacy and material compatibility with endoscopes and endoscopic accessories has been checked and approved.
- Concentration and exposure time for the cleaning agent should be taken from the instructions provided by the chemical manufacturer.
- The cleaning agents must be compatible.

**IMPORTANT!**
Do not use metal brushes for cleaning.

**IMPORTANT!**
When using a cleaning gun make sure that the rinsing pressure is not higher than 7.25 psi. Use a pressure reducing valve if necessary.

**CAUTION!**
Spraying of contaminants!
To prevent the spraying of contaminants in the vicinity, always rinse out the channels while the instrument is immersed in the cleaning solution.
Follow the relevant guidelines and directives on personal protection.
- Immerse the flexible endoscope in a RIWO BOX filled with water, then rinse out all channels to fully remove the cleaning solution.
- Then dry the all channels until only air coming out is dry.
  - with pressure-reduced, filtered compressed air or
  - with special air pumps or
  - with a syringe
- Dry outside with a lint-free disposable cloth or cotton swab.
8.2.2 Selecting the cleaning brushes

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Product no.</th>
<th>Designation</th>
<th>for the cleaning of</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>7264.691</td>
<td>Cleaning brush diam. 3 mm for instruments with working channels of diam. 2 mm and more</td>
<td>working channel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>brush length 8 mm, overall length 1000 mm</td>
<td>●</td>
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<tr>
<td></td>
<td>7321.911</td>
<td>Cleaning brush diam. 2.5 mm for instruments with working channels smaller than diam. 2 mm</td>
<td>working channel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>brush length 10 mm, overall length 1000 mm</td>
<td>●</td>
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<tr>
<td></td>
<td>7268.691</td>
<td>Cleaning brush diam. 5 mm</td>
<td>working channel</td>
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<tr>
<td></td>
<td></td>
<td>brush length 10 mm, working length 175 mm, overall length 285 mm</td>
<td>○</td>
</tr>
<tr>
<td></td>
<td>86.90</td>
<td>Cleaning brush</td>
<td>brush length 42 mm, overall length 147 mm</td>
</tr>
</tbody>
</table>

Legend: ● = allowed ○ = not allowed

8.2.3 Insertion stopcock (14), Adapter (16)

Fig. 22
- Remove the stopcock plug (16.1.1).
  - See product-specific instruction manual
- Cleaning with a short cleaning brush:
  - Stopcock plug (16.1.1)
  - Stopcock housing (16.1.2)
8.2.4 Working channel (13)

Fig. 23

- To remove any clogging or residues, carefully clean all channels with suitable cleaning brushes (see table in section 8.2.2).

**IMPORTANT!**

Cleaning the working channel (13)!

Insert the long cleaning brush into the working channel (13) only from the proximal end to the distal end without applying any force.

**Do not** pull the cleaning brush back and forth in the working channel (13) as this can result in damage to the working channel of the fiberscope.

Guide the cleaning brush through the working channel (13) only in one direction and pull back only after the brush head has been fully exposed at the distal end.

Fig. 23

- Rinse the flexible fiberscope inside and out with a cleaning solution to remove any loosened/dissolved particles.
- Reprocess the cleaning brushes.

8.3 Checks

- Carry out a check: see sections 7 and 7.1

8.4 Assembly before sterilization

**NOTE!**

Before sterilization, screw on the screw connections only loosely to allow a sufficient flow of sterilization medium.

Tighten all screw connections before use.

- Screw on the cold-light connector (4) only loosely 1–2 turns.

8.4.1 Insertion stopcock (14), Adapter (16)

Fig. 24

- Insert the stopcock plug (16.1.1) into the stopcock housing (16.1.2).
  - The stopcock plug (16.1.1) snaps into position.
- Open the stopcock plug (16.1.1).
8.5 Sterilization

8.5.1 Preparation for sterilization

**IMPORTANT!**
- The instruments must be sufficiently dry for sterilization.
- Open the irrigation, drain and insertion stopcock.
- Do not expose flexible fiberscopes to sudden temperature changes.
  - Allow the container with the flexible fiberscopes to cool down slowly to hand warm in the sterilizer.
- Follow the instructions / manual of the sterilizer manufacturer.

**Fig. 25**

**IMPORTANT!**
For EtO gas sterilization and STERRAD NX sterilization, install the pressure equalization valve (A) on the connector for leakage test and pressure equalization (10) prior to sterilization.
- Attach pressure equalization valve (A) to the connector for leakage test and pressure equalization (10).
  - Push the pressure equalization valve (A) onto the connector for leakage test and pressure equalization (10) as far as it will go and lock the twist-lock mechanism by turning clockwise.

**Fig. 25**

**IMPORTANT!**
Only attach the pressure equalization valve (A) before EtO and STERRAD NX gas sterilization.
With the pressure equalization valve (A) attached during cleaning or during immersion in disinfectant, liquid would enter into the flexible fiberscope and destroy internal components.
Unscrew the pressure equalization valve (A) after removing the sterilization packaging.

**NOTE!**
The insertion stopcock (14), adapter (16) and the luer connector (15) can also be steam sterilized using the pre-vacuum method at 270 °F.
8.5.2 Gas sterilization using ethylene oxide gas (EtO)

Under ambient conditions ethylene oxide is a gas. It is both toxic and flammable, and in conjunction with air, forms an explosive mixture over a wide range of concentrations. In animal experiments, under ambient conditions comparable to conditions of possible exposure of persons at the workplace, ethylene oxide has proven to be carcinogenic.

Most materials (mainly rubber and plastic materials) absorb ethylene oxide during exposure. Desorption is a slow process; a certain residual amount of gas therefore remains in sterile items. In accordance with ISO 10993 part 7, the ethylene oxide dose administered to a patient via devices for a single or multiple use or which have contact with the patient for no more than 24 hours must not exceed 20 mg.

Desorption depends on a multitude of factors, such as:

- Type of sterilization procedure (EtO concentration - gas exposure time),
- Inert gases,
- Material properties of the sterile items,
- Permeability of the packaging / wrapping,
- Type of storage of the sterile items,
- Temperature and frequency of air change during storage.

In desorption chambers operated at 86°F - 140°F in most cases an aeration time of several hours is sufficient. At room temperature desorption usually takes several days.

Sterilization of RICHARD WOLF Heat Sensitive Instruments using ethylene oxide gas has been proven under the following conditions:

- Sterilization temperature: 104°F ± 5°F
- Pre-vacuum: >1,6 psi ± 0,15 psi
- Relative humidity: 60% ± 10% (before gas exposure)
- Contact time: 180 minutes
- EO concentration: 1000 mg EO/l ± 50 mg/l
- EO chamber pressure: 10,9 psi ± 0,44 psi absolute
- N2 buffer: 2,2 psi ± 0,15 psi
- Number N2 purging cycles: 2
- Number of purging cycles: 4

**IMPORTANT!**

According to manufacturer’s specifications, EtO devices operating in accordance with a validated procedure in accordance with EN 1422, annex F, guarantee safe sterilization and desorption.

- Follow the device manufacturer’s instructions.

Heat sensitive RICHARD WOLF endoscopes which have been sterilized applying the conditions referred to above can be used again on the patient providing the desorption conditions listed below have been observed and 6 hours of aeration time has been allowed in accordance with ISO standards 10 993 part 7:

- Temperature: 90°F - 95°F
- Air circulation: 10 times per hour
- Air exchange: once per hour
- Desorption time: 6 hours
8.5.3 Sterilization with STERRAD®'s NX reprocessing unit

The fiberscopes can be sterilized using the Advance Cycle on the STERRAD NX.

- Follow the device manufacturer's instruction.

**IMPORTANT!**
Always put on the pressure equalization valve (see section 8.5.1) before reprocessing the fiberscope in the STERRAD NX unit.

8.6 Manual disinfection

**Fig. 26**

- For manual disinfection we recommend our RIWO BOX.
  - This system features the following advantages:
    - Thanks to integrated support points, liquid can drip of the basket ensuring that the liquid flows back into the container.

- Immerse the flexible fiberscope in a disinfectant solution.
  - Follow the disinfectant manufacturer's instructions with regard to:
    - Disinfection efficacy
    - Concentration
    - Immersion time and
    - Use life
  - To avoid mechanical damage, immerse the flexible fiberscope and accessories separately in disinfectant solution.
  - Open the irrigation, drain and insertion stopcock.
  - Fill all channels with a syringe containing disinfectant solution.
  - Cover the RIWO BOX during disinfection.

8.6.1 After disinfection

- Rinse the following with sterile water:
  - Rinse out all channels with a disposable syringe until the liquid running out is clear.
  - Insertion stopcock (14), adapter (16) and luer connector (15)

**IMPORTANT!**
If disinfection is not followed by sterilization, sterile water must be used for rinsing the inside and outside.

- Dry all channels until the air coming out is dry:
  - with pressure-reduced filtered compressed air or
  - with special air pumps or
  - with a syringe
- Dry the outside with a lint-free disposable cloth or a cotton swab.

**NOTE!**
In order to improve drying, the working channel (13) can be rinsed out with sterile 70% alcohol (ethanol, isopropanol) before drying.

**IMPORTANT!**
If flexible fiberscopes are not dried properly, micro-organisms can multiply in the residual moisture, e.g. in the channel system of the endoscope during storage, representing an infection source for patients examined subsequently. Complete drying should therefore be the aim.
8.7 Reprocessing in the event of repair

⚠️ CAUTION!
Risk of transmitting microorganisms!
In order to protect the service personnel and for safety reasons during transport and shipment, all fiberscopes returned for repair must be reprocessed in accordance with manual GA-J050.

Only if the specified reprocessing procedure would increase the damage to the fiberscope, you may send in the fiberscope in unsterile condition.
For this purpose:
Carefully wipe the outside of the videoscope with a disposable cloth soaked in cleaning disinfectant. Blow through the channels.
• Take adequate personal protection measures.
9 Technical data and order data

For additional information on the reprocessing, see Manual GA-J050 "Reprocessing of RICHARD WOLF Heat Sensitive Instruments".

<table>
<thead>
<tr>
<th>Product no.</th>
<th>Working length [mm]</th>
<th>Diameter [mm]</th>
<th>Working channel [mm / Fr.]</th>
<th>Image angle [°]</th>
<th>Viewing direction [°]</th>
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<tbody>
<tr>
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<td>450</td>
<td>1.6</td>
<td>0.6 / 1.8</td>
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<tr>
<td>7325.122</td>
<td>200</td>
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<td>0</td>
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<tr>
<td>7305.011</td>
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<td>2.5 / 7.5</td>
<td>110</td>
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</tr>
</tbody>
</table>

9.1 Deflecting the instrument tip (3)

**NOTE!**
The flexible fiberscope 7321.164 can only be deflected upwards.

<table>
<thead>
<tr>
<th>Product no.</th>
<th>Deflection angle</th>
<th>Control movement (9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7321.164</td>
<td>up: 90°</td>
<td>up: proximally</td>
</tr>
<tr>
<td>7325.122 /152 /172</td>
<td>up: 130°, down: 160°</td>
<td>up: proximally / down: distally</td>
</tr>
<tr>
<td>7305.001</td>
<td>up: 210° / down: 150°</td>
<td>up: proximally / down: distally</td>
</tr>
<tr>
<td>7305.006</td>
<td>up: 210° / down: 150°</td>
<td>up: distally / down: proximally</td>
</tr>
<tr>
<td>7305.011</td>
<td>left: 120° / right: 120°</td>
<td>left: distally / right: proximally</td>
</tr>
</tbody>
</table>
## Spare parts and accessories

<table>
<thead>
<tr>
<th>Illustration</th>
<th>Product no.</th>
<th>Designation, Technical data</th>
</tr>
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<tbody>
<tr>
<td>see Fig. 1 - Fig.4 Page 2</td>
<td>8954.765</td>
<td>Insertion stopcock</td>
</tr>
<tr>
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<td>Luer connector</td>
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<td>7305.782</td>
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<td></td>
<td>15 634.007</td>
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<td>Stone extractor, Fr. 3, WL 910 mm, modular, 4-armed</td>
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<td>8741.33</td>
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<td>8741.80</td>
<td>Flexible coagulation electrode, Fr. 3, WL 920 mm</td>
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<tr>
<td></td>
<td>7223.911</td>
<td>HF button electrode, Fr. 3, WL 980 mm</td>
</tr>
</tbody>
</table>

|              | 8741.80    | Flexible coagulation electrode, Fr. 3, WL 920 mm                                           |
|              | 7223.911   | HF button electrode, Fr. 3, WL 980 mm                                                       |
|              | 8741.33    | Stone grasping device, Fr. 3, WL 910 mm, modular, 3-armed                                   |
|              | 8741.03    | Stone extractor, Fr. 3, WL 910 mm, modular, 4-armed                                         |

|              | 829.601    | Flexible biopsy forceps, Fr. 3, WL 950 mm                                                   |
|              | 828.651    | Flexible foreign-body grasping forceps, Fr. 3, WL 950 mm                                    |
|              | 7223.60    | Flexible biopsy forceps, Fr. 3, WL 600 mm                                                   |
|              | 7223.65    | Flexible foreign-body grasping forceps, Fr. 3, WL 600 mm                                    |
|              | 8734.608   | Flexible biopsy forceps, Fr. 4, WL 850 mm                                                   |
|              | 8734.606   | Flexible biopsy forceps, Fr. 4, WL 600 mm                                                   |
|              | 8734.658   | Flexible foreign-body grasping forceps, Fr. 4, WL 850 mm                                    |
|              | 8734.656   | Flexible foreign-body grasping forceps, Fr. 4, WL 850 mm                                    |
|              | 8734.686   | Flexible grasping forceps, Fr. 4, WL 850 mm                                                |
|              | 8734.688   | Flexible grasping forceps, Fr. 4, WL 850 mm                                                |
|              | 8735.684   | Flexible grasping forceps, Fr. 5, WL 450 mm                                                |
|              | 8735.685   | Flexible grasping forceps, Fr. 5, WL 540 mm                                                |
|              | 8736.685   | Flexible mouse tooth forceps Fr. 6.5, WL 550 mm                                            |
|              | 829.055    | Flexible biopsy forceps, Fr. 6.5, WL 550 mm                                                |
|              | 829.045    | Flexible biopsy forceps, Fr. 5, WL 450 mm                                                   |
|              | 828.051    | Flexible grasping forceps, Fr. 5, WL 540 mm                                                |
|              | 829.051    | Flexible biopsy forceps, Fr. 5, WL 540 mm                                                   |

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

### 11 Operating, storage, transport and shipping conditions

<table>
<thead>
<tr>
<th>Operating conditions</th>
<th>Requirements</th>
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<tr>
<td>+10°C to -40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa</td>
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</table>

<table>
<thead>
<tr>
<th>Storage, transport and shipping conditions</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>-20°C to +60°C, 10% to 90% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE!**
To prevent damage during transport or shipment of the products we recommend using the original packaging material.

### 11.1 Disposal of product, packaging material and accessories

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

* For further information please contact the manufacturer.
12 Warranty and Customer Service

Richard Wolf guarantees our instruments to be free from any defects in materials and workmanship under normal use and service for one year. Richard Wolf general terms and conditions may be found on the back of our invoice.

Parts delivered separately by Richard Wolf are subject to all of the same general terms and conditions for our products, including the limitations of warranty and liability.

All products should be returned to Richard Wolf for any necessary or desired repair or part replacement. No product repair or part replacement should be done other than by Richard Wolf unless the care and instruction manual or other written information indicates that repair or part replacement is authorized. If authorized, parts must be replaced only by parts supplied or specified by Richard Wolf, and product repair and part replacement must be done in strict conformance with Richard Wolf specifications and instructions for repair and part replacement, including post replacement testing and recalibration. Failure to follow this requirement in any way can be dangerous to you, your personnel and your patients and voids the warranty for the product repaired or the product in which the part was replaced and if the part was supplied by Richard Wolf, for that part.

Delivery by Richard Wolf of technical documents such as circuit or other design diagrams does not constitute authorization for product repair or part replacement. Richard Wolf instruments and other products should never be modified or altered under any circumstances.

Contact Richard Wolf if you have any question (1) whether replacement of a part or a repair is authorized by Richard Wolf, or (2) whether you have complete instructions and specifications for part replacement or repair.

These instructions do not attempt to cover all details or variations in equipment, nor to provide for every possible contingency to be met in connection with installation, operation, or maintenance. Should further information be required or should problems arise which are not covered sufficiently for the purchaser’s purpose, the matter should be referred to Richard Wolf Medical Instruments Corporation.

Our national sales and service offices, as well as our manufacturing facility, are located in Illinois. Trained manufacturer’s representatives are located throughout the U.S. to serve you. For any questions regarding these instruments, or to place an order, contact Richard Wolf customer service department at 847-913-1113 or 800-323-WOLF (9653).

INSTRUMENT ORDERING POLICY

Richard Wolf reserves the right to make substitutions, if necessary, without prior notice.

REPAIR POLICY

Defective merchandise will be repaired or replaced at no charge to the customer, provided the customer delivers such defective merchandise prepaid. Any repairs, maintenance or servicing of Richard Wolf merchandise by anyone other than a factory authorized representative will render our warranty null and void.

REPAIR SHIPMENTS

When returning your instrument for repair, we suggest that you prevent shipping damage to the instrument by reusing the box that it was originally shipped in. Richard Wolf also recommends that the instrument be insured for an amount to cover the cost of replacement.

IMPORTANT

For general safety and health reasons, Richard Wolf requires that you clean and sterilize all instruments before returning them for repair. If instruments are received in an unsanitary condition, Richard Wolf will clean and sterilize each instrument and add a $100.00 cleaning charge for each instrument requiring cleaning.