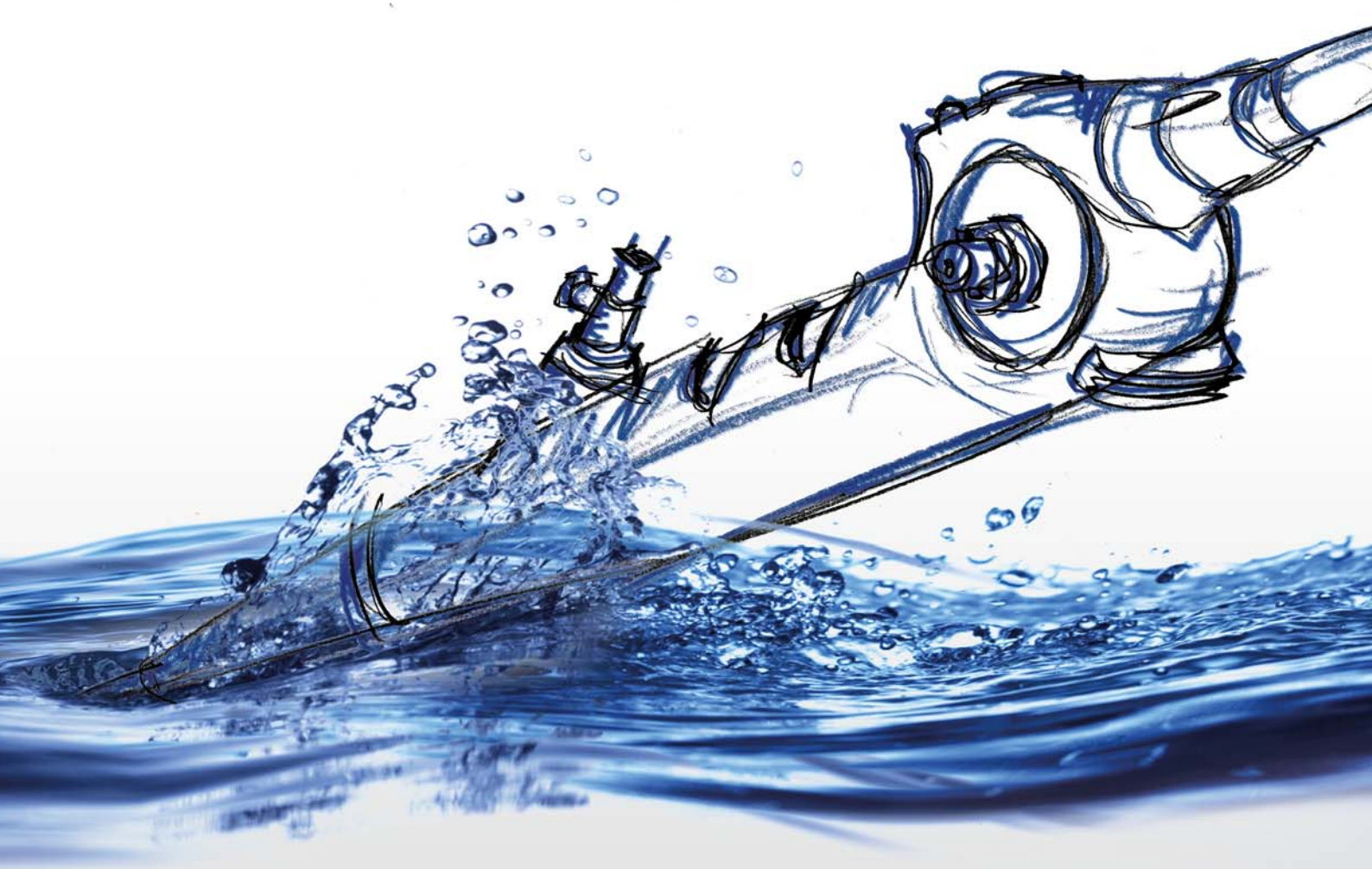
RICHARD WOLF

spirit of excellence

Manual



Reprocessing
of
RICHARD WOLF
Heat-Sensitive Instruments

GA-J050 / en / 2014-05 V7.0 / PDI 13-6891

RICHARD WOLF
spirit of excellence
Hygiene

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⚠ Important general notes and instructions for use ⚠

The reprocessing must be carried out with suitable, state-of-the-art procedures by qualified medical personnel following the manufacturer's notes and instructions. Reprocessing must be traceable and reproducible. A classification and risk assessment must be carried out. The individual steps and responsibilities must be listed and documented in writing.

Requirements for reprocessing:
Basic requirements are defined in

- *The **Medical Product Law** (MPG)*
- *The **Medical Product Operator Directive** (MedBetreibV)*
- *The **Agreements on Quality Assurance** (QA)*
- *The **European Standards** (DIN EN)*
- *The appropriate **Recommendations on Hospital Hygiene issued by the Robert Koch Institute** and*
- *The **current rules and regulations issued by the Employers' Liability Insurance Associations.***

The product must only be used as intended following the instruction manual by adequately trained and qualified medical personnel. Maintenance and repair must be 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 met. The product must not be altered in any way.

Reprocess the product in accordance with the manual before every use and before return shipment to protect the patient, user and third parties.

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 on receipt, check the product and its accessories for completeness and possible damage. Should the shipment give rise 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.

Safety instructions and levels of danger

Symbol	Level of danger
⚠	*WARNING!* Failure to observe can result in death or extremely serious injuries.
⚠	*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!* User tips for optimum device use and other useful information.

Contents

1 General Information

1.1 Manuals / Instructions for use

RICHARD WOLF provides the following different manuals / instructions for safe use and correct reprocessing of RICHARD WOLF products and accessories:

- ◇ **GA-J020**
  Manual “Reprocessing of RICHARD WOLF Heat-Stable Instruments"
- ◇ **GA-J050**
  Manual “Reprocessing of RICHARD WOLF Heat-Sensitive Instruments”
- ◇ **Product-specific instructions for use**
  These instructions describe the specific use of the product with all the necessary data and information.
- ◇ **The current version of the manuals / instructions for use**
  Continuous new and further developments of RICHARD WOLF products and technological advances mean that the manuals / instructions for use have to be updated at regular intervals.
  Please check the number of the latest version by checking the last numbers of the index on the front page.

  Example:

  GA-J050 / en / 2014-05 V7.0 /...

  You may call up the latest version from our website and download it, or request the document from us.

  www.richard-wolf.com

☞ ***NOTE!***

*In addition to these manuals / instructions for use we recommend the following brochure, published by the "AKI" working group (**A**rbeits**k**reis **I**nstrumentenaufbereitung).*

Instrument reprocessing
Reprocessing instruments maintaining their value

*The brochure is available from RICHARD WOLF or can be downloaded free of charge from the **www.a-k-i.org** website.*

1.2 Material compatibility / Efficacy test

RICHARD WOLF has tested the low-temperature sterilization procedures described in section 1.10 **"Overview of reprocessing / material compatibility"**, with regard to their material compatibility.

The effectiveness of steam sterilization using the fractional pre-vacuum method in accordance with DIN EN 285 / ISO 14937 has been proven.

1.3 Chemicals for reprocessing

The chemicals for the reprocessing of heat-stable and heat-sensitive instruments [rigid telescopes, flexible endoscopes / videoscopes (fiberscopes) and instruments] approved by RICHARD WOLF with regard to their material compatibility are listed and can be downloaded from our website.

www.richard-wolf.com/reprocessing-chemicals

This overview is updated at regular intervals.

1.4 Questions concerning RICHARD WOLF products

If you have questions concerning RICHARD WOLF products or their reprocessing, please contact our customer service department.

RICHARD WOLF SERVICE
www.richard-wolf.com/customer-service

1.5 Basic notes and instructions

⚠ ***WARNING!***

Creutzfeldt-Jakob Disease!

If the patient is suspected of having the Creutzfeldt-Jakob disease (CJD) or a variant of the Creutzfeldt- Jakob disease (vCJD) or the latter 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 guidelines and regulations.

☞ ***IMPORTANT!***

Rental instruments must not be used in pathology or veterinary medicine.

☞ ***IMPORTANT!***

During the entire reprocessing phase, be sure to follow the guidelines on the protection of the workplace and on the protection of the staff, e.g. TRBA 250.

☞ ***IMPORTANT!***

Do not use physiological saline solution for immersion or rinsing as this can cause corrosion of metal surfaces.

Avoid frequent changes of reprocessing methods as well as cleaning agents and disinfectants as interactions between the latter can cause damage to the product.

Preclean the instruments immediately after use at the point of use and reprocess as soon as possible.

➧ *See section 4* ***"Preparation of instruments at the point of use"***

1.6 Brand new products

☞ ***NOTE!***

Before reprocessing remove all protection foils and shipping locks or clips from the products and the accessories.

Reprocess the products and the accessories at least once before the first use.
The certified procedures are described in the following sections or in the product-specific instructions for use.

1.7 Disposable item

Disposable items must be

- used only once.
- discarded after use

1.7.1 Unsterile disposable items

Reprocess unsterile disposable items before use.

- See product-specific instructions for use

⚠ *WARNING!*

Multiple use of disposable items!

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

Multiple uses can impair and or change the product properties and therefore endanger the patient, user and others.

Possible dangers / risk factors are described in the product-specific instruction manuals and must be observed.

In the case of multiple uses, the product responsibility lies with the user.

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

1.7.2 Sterile disposable items

⚠ *WARNING!*

Do not reprocess disposable items!

The service life of products marked as disposable, i.e. for single use only, is 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 / risk factors are described in the product-specific instruction manuals and must be observed.

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

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

☞ *IMPORTANT!*

The sterility of sterile products is only guaranteed if the packaging hasn't been damaged or opened.

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

1.8 Characteristic features of steam sterilizability

The steam sterilizability of RICHARD WOLF products can be identified, e.g. from the product number:

◇ **Steam sterilizable**

- Identification feature: the product numbers begin with **"8"**
  Example: **8**654.422

◇ **Not steam-sterilizable**

- Identification feature: the product numbers begin with **"4"**
  Example: **4**840.501

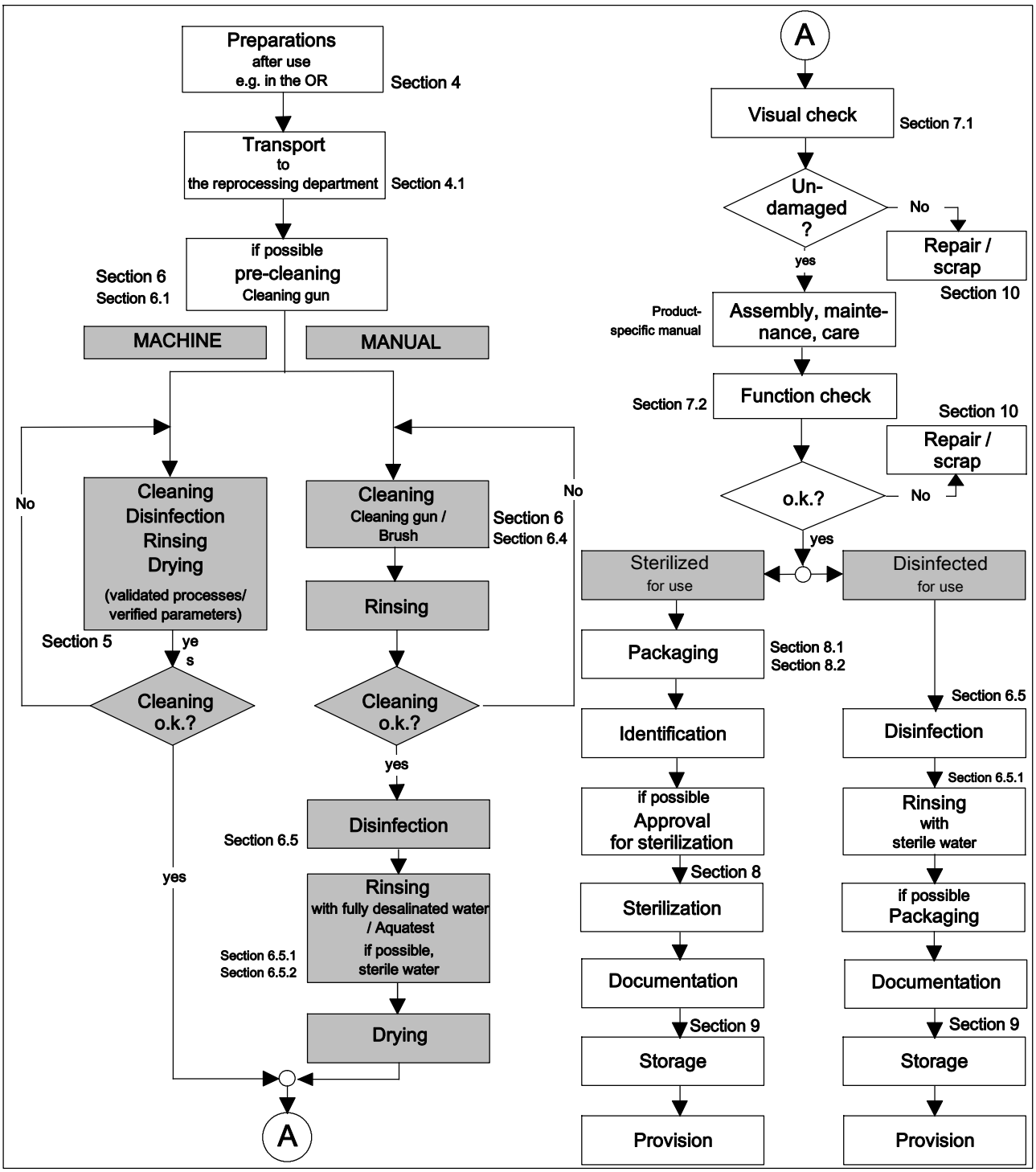
☞ *IMPORTANT!*

*For the reprocessing and/or sterilizability of products with product numbers **not** starting with **"8"**, please refer to the product-specific manuals. Follow these manuals.*

1.9 Instrument reprocessing

The products and accessories can be reprocessed manually or machine-reprocessed in a washer/disinfector. For validation reasons, machine reprocessing is preferred.

The following overview is a schematic of the sequence of reprocessing steps for heat- sensitive instruments - in the following descriptions called **"Flexible Endoscopes"**. The sections mentioned refer to the corresponding methods and procedures.



1.10 Overview of reprocessing / material compatibility

PROCEDURES		PRODUCTS	Flexible endoscopes	Accessories 03)						Suction / Biopsy connector / Laser adjustment unit				Leak-age tester	Cleaning brushes	
				Flexible forceps	Flexible coagulation button electrode	Stone extractor Stone grasper	Disposable, Sterile	Disposable, Unsterile 05)	Rubber bulb 103.00 Double bulb 127.00	Valves	Seals, unsterile	Adapter (stopcock plug)	Laser adjustment unit	Tube fitting, Twist-lock	Reprocessable	Single use
Preparation at the point of use		Wipe outside, rinse out inside	●	●	●	●	○	○	○	●	●	●	●	○	○	○
	Condition	Wet preparation at the point of use	●	●	●	●	▲	▲	○	●	●	●	●	●	●	▲
		Dry preparation at the point of use	●	●	●	●	▲	▲	●	●	●	●	●	●	●	▲
Decontamination	Preparation	Leakage test	●	○	○	○	○	○	○	○	○	○	○	●	○	○
	Cleaning	Manual	●	●	●	●	○	●	●	●	●	●	●	●	●	○
		Machine	●	●	●	●	○	■	●	●	●	●	●	●	●	○
		Ultrasound 03)	○	●	●	●	○	○	○	●	○	●	●	○	●	○
		Alkaline	○	●	●	●	○	■	○	●	●	●	●	●	●	○
		Containing citric acid	○	●	●	●	○	■	○	●	●	●	●	●	●	○
		Neutral / enzymatic	●	●	●	●	○	■03)	●	●	●	●	●	●	●	○
		Containing peracetic acid	●	●	●	●	○	○	○	●	●	●	●	●	●	○
	Rinsing 01)		●	●	●	●	○	●	●	●	●	●	●	●	●	○
	Dis-infecting 02)	Chemical max. 60°C	●	●	●	●	○	●	●	●	●	●	●	●	●	○
		Thermal max. 93°C	○	●	●	●	○	○	●	●	●	●	●	●	●	○
	Drying	T_{max} in °C	60°	100°	100°	100°	○	■	100°	100°	100°	100°	100°	100°	100°	○
Maintenance, checks		After decontamination	■	■	■	■	○	■	●	■	■	■	■	■	■	○
Sterilization	Steam sterilization 03)															
	Steam	Fractional pre-vacuum method 134°C / 273°F 132°C / 270°F	○	●	●	●	○	■	○	●	●	●	●	●	●	○
	Low-temperature sterilization															
	Hydrogen per-oxide plasma	STERRAD® 50, 100S, 200	●	●	●	●	○	■	○	●	●	●	●	●	●	○
		STERRAD® NX™,100NX™	●	●	●	●	○	■	○	●	●	●	●	●	●	○
	Gas	Low-temperature steam and formaldehyde (LTSF)	●	●	●	●	○	■	○	●	●	●	●	●	●	○
		Ethylene oxide (EO)	●	●	●	●	○	■	●	●	●	●	●	●	●	○
		Hydrogen peroxide (STERIS V-PRO™ 1, V-PRO 1 Plus, V-PRO maX)	●	●	●	●	○	■	●	●	●	●	●	●	●	○
	Peracetic acid 04) (Just in time)	STERIS SYSTEM 1® STERIS SYSTEM 1E™	●	●	●	●	○	○	○	●	●	●	●	●	●	○

x) **Starting with product numbers "8..." / "4..."**

01) Fully desalinated water is recommended for the final rinsing

02) Chemicals for reprocessing (see section 1.3)

03) Detailed reprocessing information (see GA-J020)

04) Products are not packed sterile (see section 8.2.5)

05) Before use

Legend:
- ● Permissible
- ○ Not permissible / not necessary
- ▲ Discard disposable item
- ■ See product-specific instructions for use

2 Product variants

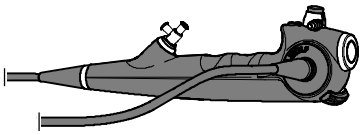
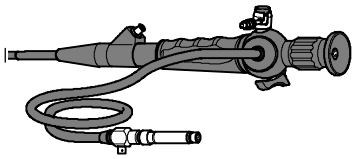
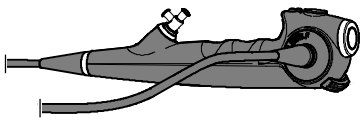
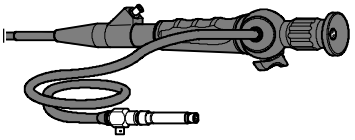
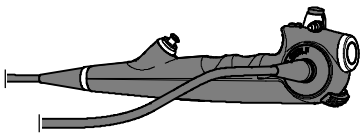
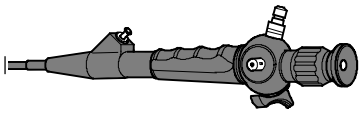
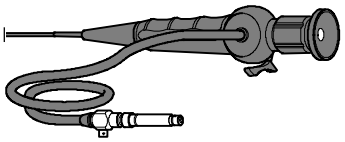
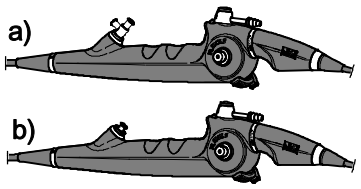
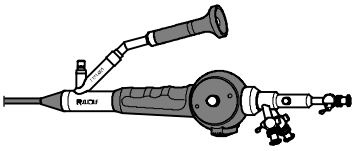
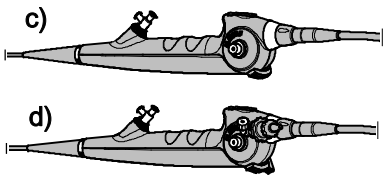
VIDEOSCOPES Urology / ENT	FIBERSCOPES Urology / Gynecology	FIBERSCOPES ENT
 **Flexible Video Urethro-Cystoscope / PDD Video Urethro-Cystoscope** with working channel and suction valve	 **Flexible Fiber Uretero-Renoscope** with working channel	 **Flexible Bronchoscope / DAFE Bronchoscope** with working channel and suction valve
 **Flexible Video Urethro-Cystoscope** with working channel	 **Flexible 2-Channel Continuous Irrigation Laser URS** with working channel and laser fiber channel	 **Flexible Nasopharyngo-Laryngoscope** with working channel
 **Flexible Video Bronchoscope / DAFE Video Bronchoscope** with working channel and suction valve	 **Flexible Urethro-Cystoscope / Hysteroscope** with working channel	 **Flexible Nasopharyngo-Laryngoscope**
 **Flexible** **a) LED Video Urethro-Cystoscope** **b) LED Video-Bronchoscope** with working channel and suction valve	 **Flexible Fiber Uretero-Renoscope** with working channel	
 **c) BOA Vision Flexible Sensor URS** with working channel **d) COBRA Vision Flexible Sensor URS** with working channel and laser fiber channel		

Fig. 1

2.1 Illustration

The reprocessing is described by example of the flexible video-urethro-cystoscope with working channel and suction valve.

Depending on how the product variant is equipped, the description shall apply by analogy.

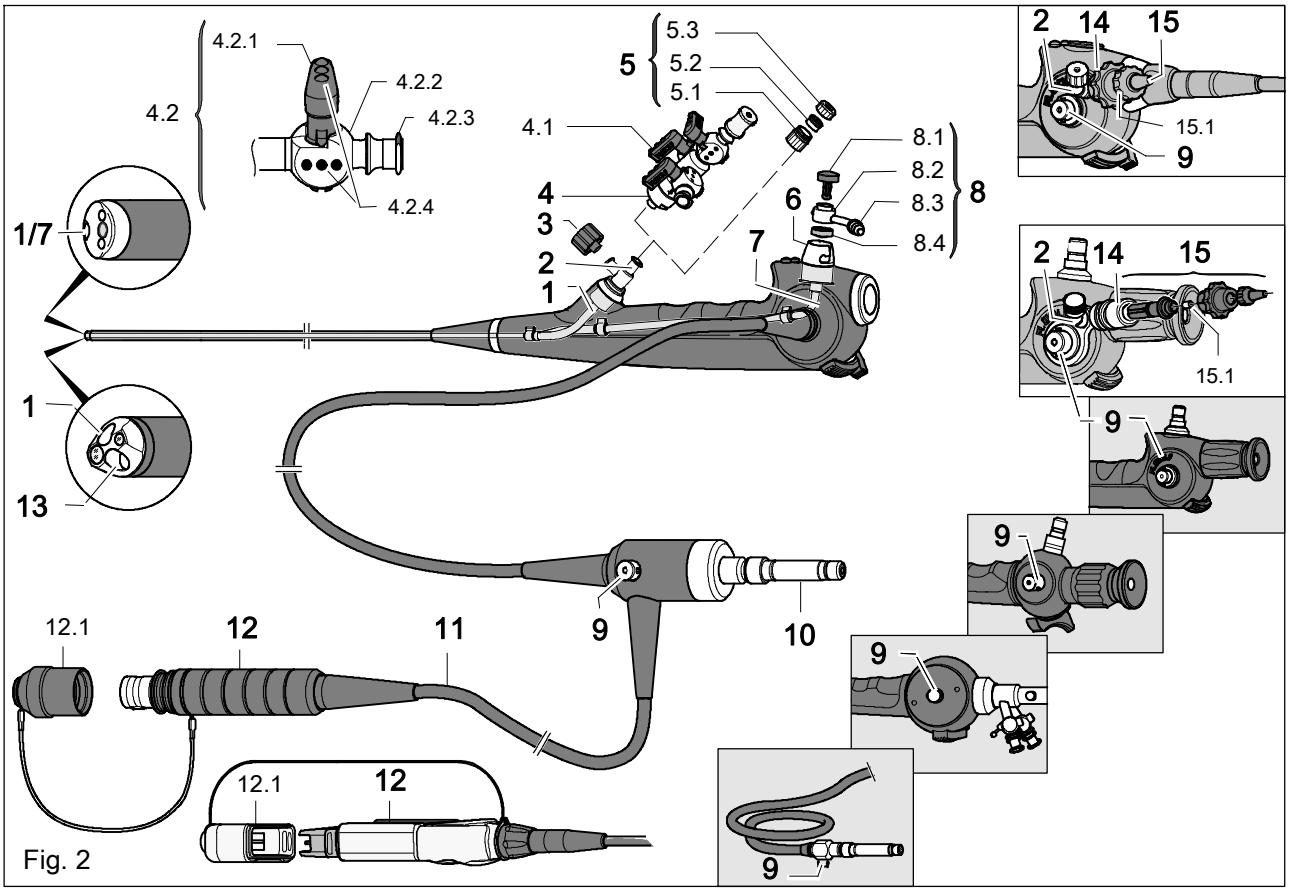


Fig. 2

2.1.1 Legend and identification

Item	Designation	Item	Designation
1	**Working channel**	**8**	**Valve element**
2	**Luer connector**	8.1	Valve tappet
3	**Luer lock cap**	8.2	Valve insert
4	**Adapter**	8.3	Tube connector
4.1	Irrigation, drain and insertion stopcock	8.4	Sealing membrane (disposable product)
4.2	Stopcocks, complete for attachment with removable stopcocks	**9**	**Connector for leakage test and pressure equalization**
4.2.1	Stopcock plug	**10**	**Adapter, projector to light cable**
4.2.2	Stopcock housing	**11**	**Camera cable**
4.2.3	Luer connector	**12**	**Camera plug**
4.2.4	Passage identification on stopcock housing, stopcock plug	12.1	Protection cap for camera plug
5	**Biopsy valve**	**Only for 2-channel continuous irrigation laser URS**	
5.1	Valve housing	**13**	**Laser fiber channel**
5.2	Sealing valve / transparent (disposable product)	**14**	**Receptacle for laser adjustment unit**
5.3	Sealing cap	**15**	**Laser adjustment unit, complete**
6	**Valve holder**	15.1	Fastening element, orange (disposable product)
7	**Suction channel**		

3 Water quality

The water quality used for product reprocessing has a great influence on preserving the product value.

Depending on the water hardness and temperature, differing drinking water qualities (types and concentrations of ingredients) can cause difficult-to-dissolve hardness deposits, corrosion and discoloration on the products.

The concentration of the water ingredients varies depending on the source and type of drinking water treatment. When water evaporates these ingredients remain in the form of a salt crust. Amongst these ingredients chlorides are particularly critical.

☞ ***IMPORTANT!***

Excessive chloride concentrations cause pitting corrosion on stainless steel!

To avoid this when machine-cleaning products, we recommend using fully demineralized water of a defined water quality in accordance with DIN EN 285, Appendix B for the final rinsing.

3.1 Ion exchanger for full demineralization

When using ion exchangers for full demineralization please note that exceeding the regeneration cycle can cause silicic acid (silica) to break through, which will cause deposits.

Timely regeneration of the exchanger can avoid this. For this purpose please follow the manufacturer's instructions.

Source:

Instrument reprocessing
Reprocessing instruments maintaining their value
www.a-k-i.org

☞ ***NOTE!***

Fully demineralized water with the following microbiological drinking water quality should be used for final rinsing:

- *The total bacteria count must not exceed the value of 100 CFU[*)] / ml during an incubation period of 44 4 ± hours at 36 ± 1° C.*
- *Escherichia coli must not be present in 100 ml.*
- *Pseudomonas aeruginosa must not be present in 100 ml.*

[*)] colony-forming units

Source:

Directive on the quality of water intended for human consumption (German Drinking Water Ordinance - TrinkwV 2001)
www.gesetze-im-internet.de/trinkwv_2001/anlage_3_35 or anlage_5_377

The national guidelines of the Drinking Water Ordinance must be followed.

4 Preparation of the instruments at the point of use

☞ ***NOTE!***

Drying of contaminant residues (blood, tissue particles, drugs, etc.) makes reprocessing difficult and increases the danger of corrosion.
The measures listed in the following must be carried out during use at the instrument table or immediately after:

Fig. 3

◇ *Flexible endoscope*

- ***Outside*** *- Wipe the outside of the instruments with a lint-free disposable cloth soaked in a certified cleaning agent / disinfectant.*
- ***Inside*** *- Rinse the inside with a certified cleaning / disinfectant solution.*

☞ ***IMPORTANT!***

To prevent the plastic outer coating from wrinkling or folding over, apply minimal pressure when wiping the distal end of the hose.
In the case of wrinkling or folding over ***immediately*** *fold back and smooth out the plastic outer coating carefully.*

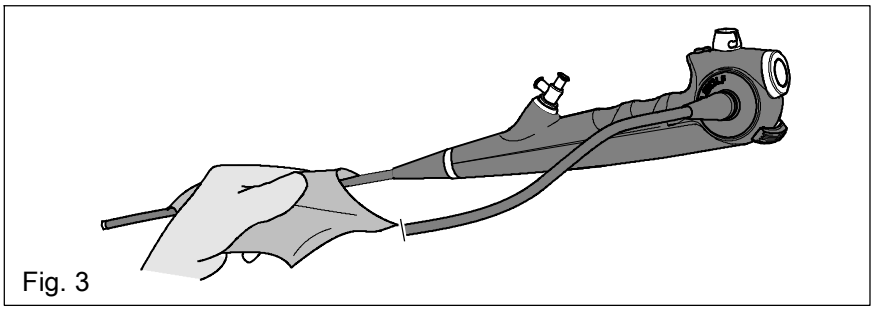


Fig. 3

◇ Carefully put down instruments in order to avoid damage.

☞ ***IMPORTANT!***

Carry out a leakage test immediately after each use and before each reprocessing.

- *See section 6.3 "Manual leakage test"*

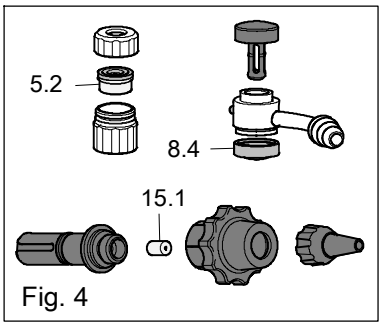


Fig. 4

◇ Dismantle flexible endoscope as far as necessary.

- See product-specific instructions for use

Fig. 4

◇ Discard disposable items immediately.

- Sealing valve (5.2)
- Sealing membrane (8.4)
- Fastening element, orange (15.1)

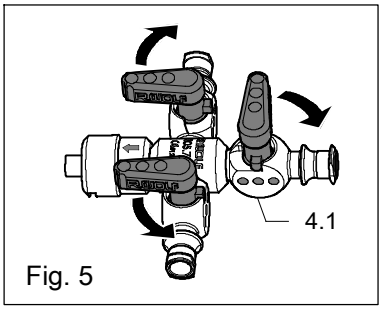


Fig. 5

Fig. 5

◇ Open inlet, outlet and instrument port stopcock (4.1).

4.1 Transport

The parts can be transported to the reprocessing rooms either under wet or in dry conditions, depending on the reprocessing method used.

4.1.1 Dry preparation at the point of use

In the case of machine reprocessing in a washer/disinfector, dry preparation at the point of use should be the method of choice, because residues of the wet preparation solution (disinfectant) may jeopardize the cleaning result in the machine.

◇ Carry out preparatory measures at the point of use: see section 4

4.1.2 Wet preparation at the point of use

In the case of manual reprocessing, wet preparation at the point of use is recommended in order to avoid contaminant residues drying on the instruments and prevent microbial carry-over.

For wet decontamination use a certified combined cleaning and disinfectant solution with proven disinfection efficacy.

For this purpose use the certified (approved) compatible agents as used for subsequent cleaning and disinfection.

4.1.3 Storage systems

We recommend using the storage systems intended for transit in order to ensure safe and unproblematic transport to reprocessing.

For further information please see:

- Section 11 **"Accessories for reprocessing"**
- RICHARD WOLF catalog pages **"Hygiene - Reprocessing"**

4.2 Preparatory measures for machine and manual reprocessing

A contaminated camera plug (12) must be reprocessed manually before installing the protective cap (12.1).

◇ Immerse the camera plug (12) in a certified compatible cleaning and disinfectant solution.

◇ Then rinse with sterile water.

◇ Dry the outer surfaces with a lint-free disposable cloth, dry the contacts inside with a cotton swab.

- Residual moisture in the contacts can impair signal transmission (e.g. interruptions, poor contacts).

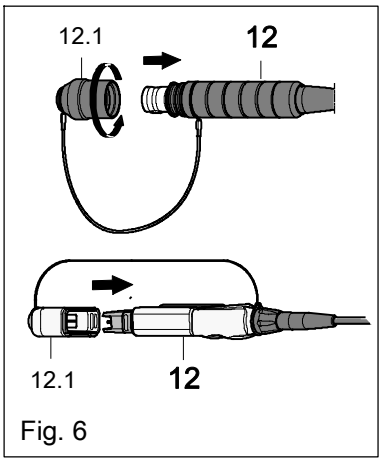


Fig. 6

Fig. 6

◇ Screw or install the protective cap (12.1) on the camera plug (12).

☞ ***IMPORTANT!***

Reprocess the camera plug (12) of flexible endoscopes only with the protection cap (12.1) in place!
If liquid enters the camera plug (e.g. because you forgot to put the cap on) carefully rinse out the plug with clear water and dry carefully (with compressed air if necessary).

5 Machine reprocessing

☞ ***IMPORTANT!***

Before every machine reprocessing, the notes in the sections 6 and 6.1 must be observed and the following operations must be performed:

- *Carry out manual leakage test (see section 6.3)*
- *Pre-clean flexible endoscope manually (see section 6.4)*

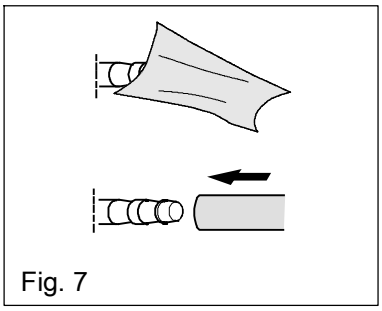


Fig. 7

Instrument connectors

Fig. 7

◇ Treat instrument connections, which are covered by connecting tubes with a certified cleaning disinfectant solution before placing in the washer-disinfector (cleaning and disinfection machine for flexible endoscopes).

◇ Finally rinse off with water

☞ ***IMPORTANT!***

◇ *Only use a washer-disinfector (cleaning and disinfection machine for flexible endoscopes).*

◇ *The certified cleaning agent and disinfectant must be compatible with each other, with the procedure and with the flexible endoscope and the endoscopic accessories.*

◇ *In accordance with DIN EN ISO 15883 the user must validate the machine reprocessing procedures used.*

◇ *Do not use disinfectants containing peracetic acid without corrosion protection, phenols or chlorine components for the reprocessing of RICHARD WOLF products.*

5.1 Auxiliary resources required

◇ Lint-free disposable cloth and cotton swab

◇ Cleaning brushes

- See section 6.4

◇ Storage systems

- We recommend using the RIWO BOX (see section 11).

◇ Washer-disinfector unit

- Observe the notes / instructions for use of the washer-disinfector unit manufacturer.
- Observe the notes in section 1.10 **"Overview on reprocessing / material compatibility"**.

5.2 Heat-sensitive instruments

For machine reprocessing of heat--sensitive instruments we recommend using a **chemo-thermal** or a **chemical procedure**.
In the **chemo-thermal procedure** the disinfection stage is carried out by adding disinfectant and increasing the temperature to 60°C (140° F).
In the **chemical procedure** the disinfection stage is carried out by adding disinfectant and without temperature exposure.

5.2.1 Chemo-thermal procedure

☞ *IMPORTANT!*

The following process parameters must be complied with:

- *Irrigation pressure: max. 0.9 bar (13.0 psi)*
- *Temperature: max. 60°C (140° F)*

5.2.2 Chemical procedure

☞ *IMPORTANT!*

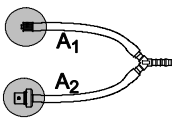
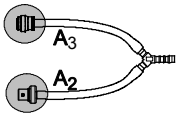
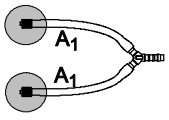
The following process parameters must be complied with:

- *Irrigation pressure: max. 0.9 bar (13.0 psi)*

5.3 Connect flexible endoscope to washer-disinfector unit

Not necessary for pressure chamber devices.
For machine reprocessing of the various flexible endoscopes, use the compatible rinsing set for machine recleaning, alternatively use rinsing tubes with corresponding fittings / adapters.

◇ After connecting, check that the connections are tightly connected.

Illustration	Product no.:	Designation
RICHARD WOLF adapter system		
	163.907	**Rinsing set II** for flexible • Bronchoscope • DAFE Bronchoscope
	163.908	**Rinsing set III** for flexible • Video Bronchoscope • DAFE Video Bronchoscope • LED Video Bronchoscope
	163910	**Rinsing set V** double luer connector for T-connection of flexible • Fiber Uretero-Renoscope • Video Urethro-Cystoscope • PDD Video Urethro-Cystoscope • LED Video Urethro-Cystoscope • 2-channel continuous irrigation laser URS (2 x rinsing set V) • BOA Vision Flexible Sensor URS • COBRA Vision Flexible Sensor URS (2 x rinsing set V) • Attachment (and additional rinsing tube)
Connectors / adapters **See section 11 "Accessories - reprocessing"**		
	886.00	**Luer lock tube fitting (A_1)**
	15028.083	**Connector (A_2)**
	15028.103	**Connector (A_3)**
	163914	**Adapter** for • 2-channel continuous-irrigation laser URS • COBRA Vision Flexible Sensor URS

5.3.1 Rinsing set II (163.907)

5.3.1.1 Connection to bronchoscopes

Fig. 8

◇ Connect rinsing set II to the luer connector (2) and valve holder (6) and connect to the washer-disinfector unit.

➧ Lock the connector (15028.083) to the valve holder (6) using the twist-lock mechanism.

◇ Alternatively, individual rinsing tubes from the washer-disinfector unit can also be used.

➧ Connect rinsing tube with
- Luer lock tube connector (886.00) for the luer connector (2)
- Fitting (15028.083) for valve holder (6)

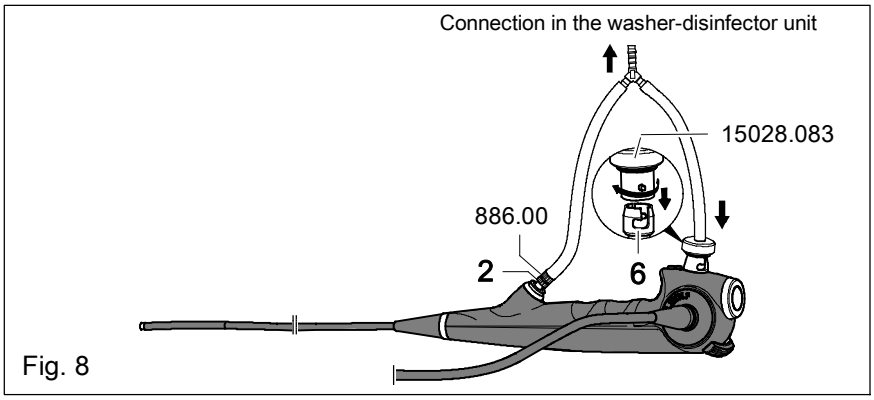


Fig. 8

5.3.2 Rinsing set III (163.908)

5.3.2.1 Connection to video bronchoscopes

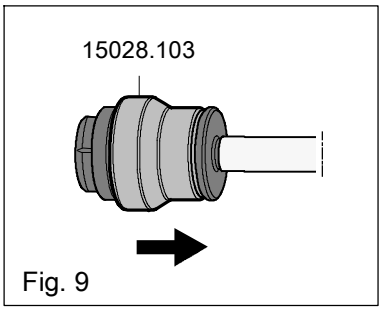


Fig. 9

Fig. 9

◇ Push the connector (15028.103) to the unlocked position.

Fig. 10

◇ Connect rinsing set III to the luer connector (2) and valve holder (6) and connect to the washer-disinfector unit.

◗ Lock the connector (15028.103) in place by pushing forward.

◗ Lock the connector (15028.083) to the valve holder (6) using the twist-lock mechanism.

◇ Alternatively, individual rinsing tubes from the washer-disinfector unit can also be used.

◗ Connect rinsing tube with
- Fitting (15028.103) for luer connector (2)
- Fitting (15028.083) for valve holder (6)

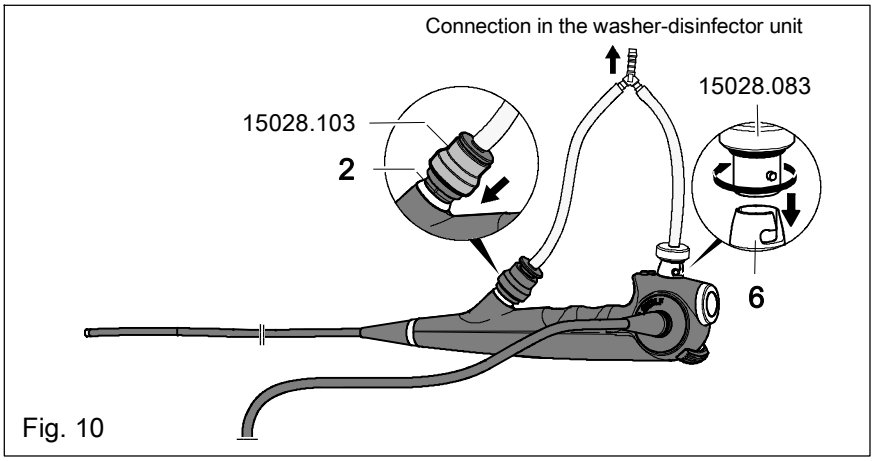


Fig. 10

5.3.3 Rinsing set V (163910)

5.3.3.1 Connection to video urethro-cystoscopes

Fig. 11

◇ Connect the rinsing tube to the connector (15028.083).

◇ Connect rinsing set V to the luer connectors (2), connect preassembled rinsing tube to the valve holder (6), and connect to the washer-disinfector unit.

◗ Alternatively, individual rinsing tubes from the washer-disinfector unit can also be used with the luer lock connector (886.00) at the luer connectors (2).

◗ Lock the connector (15028.083) to the valve holder (6) using the twist-lock mechanism.

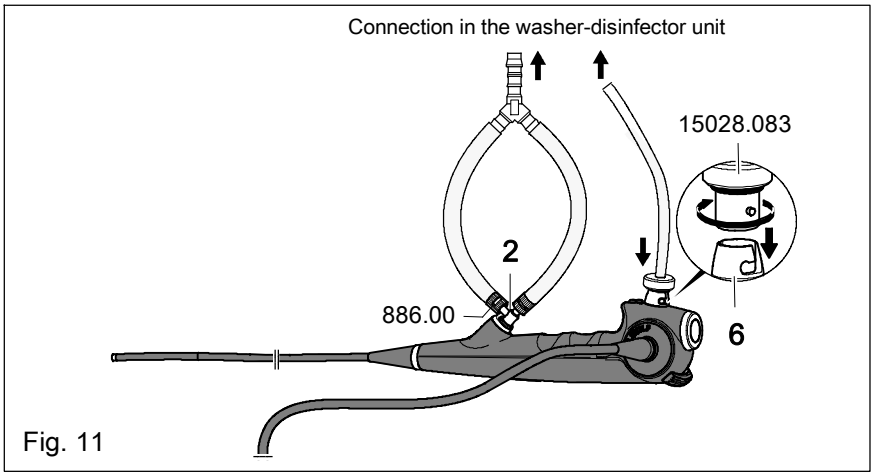


Fig. 11

5.3.3.2 Connection to fiber ureterorenoscope / BOA Vision Flexible Sensor URS

Fig. 12

◇ Connect the rinsing set V to luer connectors (2) and connect to the washer-disinfector unit.

◗ Alternatively, individual rinsing tubes from the washer-disinfector unit can also be used with the luer lock connector (886.00) at the luer connectors (2).

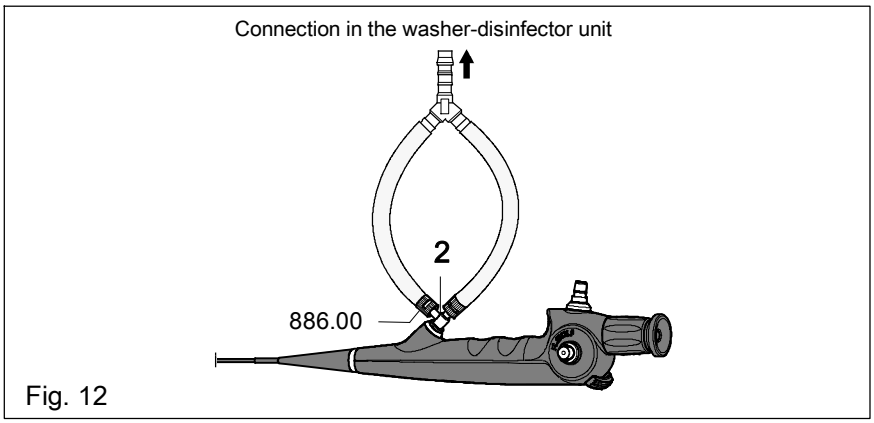


Fig. 12

5.3.3.3 Connection to 2-channel continuous-irrigation laser URS / COBRA Vision Flexible Sensor URS

Using two rinsing sets V

Fig. 13

◇ Connect the rinsing sets V to luer connectors (2) and connect to the washer-disinfector unit.

◗ Alternatively, individual rinsing tubes from the washer-disinfector unit can also be used with the luer lock connector (886.00) at the luer connectors (2).

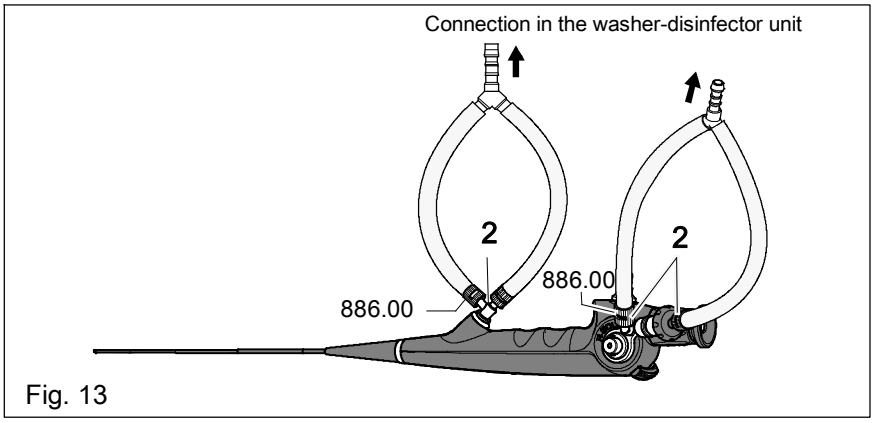


Fig. 13

5.3.3.4 Connection to adapter (4)

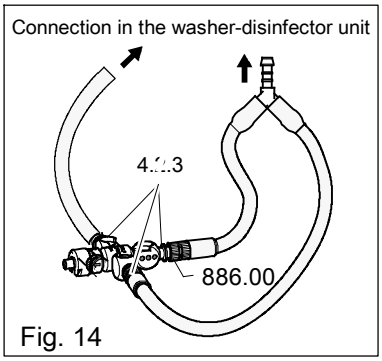


Fig. 14

Fig. 14

◇ Connect rinsing sets V and additional rinsing tube with luer lock tube (886.00) at luer connectors (4.2.3) and connect with the washer-disinfector.

◗ Alternatively, individual rinsing tubes from the washer-disinfector can also be used with the luer lock tube connector (886.00) at luer connectors (4.2.3).

5.4 Connection for automatic leakage tester

☞ ***NOTE!***

When carrying out the automatic leakage test please observe the following:

- *Use the adapter (15092.102) when using the washer-disinfector with integrated leakage test or ask the relevant washer-disinfector manufacturer for the corresponding adapter.*
- *Maximum test pressure 0.5 bar (7.25 psi)*
- *The adapter (163.905) was specially designed for the washer-disinfector unit from mfr. Olympus.*
- *Observe the information provided by the manufacturer of the washer-disinfector unit.*

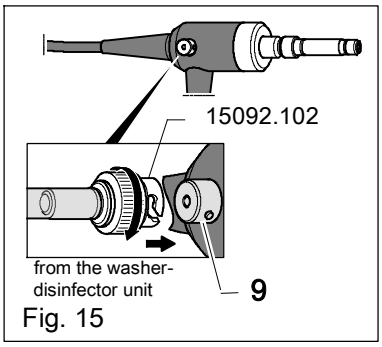


Fig. 15

Fig. 15

◇ Connect adapter (15092.102) with the connection tube of the leakage test of the relevant washer-disinfector unit under dry conditions and screw on the instrument-side connector for the leakage test and pressure equalization (9).

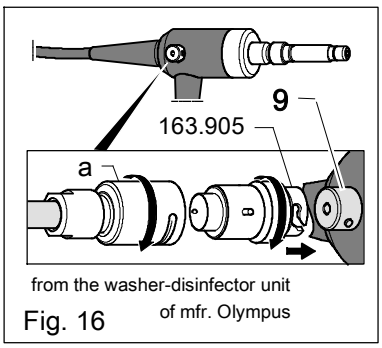


Fig. 16

Fig. 16

◇ Connect adapter (163.905) with the fitting (a) of the leakage tester from the washer-disinfector of mfr. Olympus – under dry conditions – and screw on the instrument-side connector for the leakage test and pressure equalization (9).

◇ Check for secure connections.

☞ ***NOTE!***

If the machine does not allow an integrated leakage test, carry out a manual leakage test before reprocessing (see section 6.3).

5.5 After machine reprocessing

◇ Remove adapter (163.905) from instrument-side connector.

◇ Check for cleanliness:

- Any parts that are not completely clean must be cleaned again manually.

◇ Replace defective parts.

◇ Further checks to be performed:

- See section 7
- See product-specific instructions for use

5.6 Storage systems

◇ Remove the silicone peg mats from the RIWO system trays.

◇ RIWO System Trays and separate silicone peg mats can be reprocessed up to 93°C (200°F) using the thermal method.

6 Manual reprocessing

☞ ***IMPORTANT!***

During the entire reprocessing process you must observe the following:

- *Do not bend flexible instrument sheath or store in a tight radius (minimum 150 mm diameter).*
- *Brake (tilt lever) must be released at the control lever to fix the instrument tip in angled position.*

6.1 Manual cleaning and disinfection

⚠ ***CAUTION!***

Spray contamination!

In order to avoid spraying microorganisms in the surrounding area, channels must always be rinsed below the surface of the certified cleaning solution.

Follow the applicable staff protection guidelines.

☞ ***IMPORTANT!***

Do not clean flexible endoscopes in ultrasonic baths!

☞ ***IMPORTANT!***

Use only disinfectants whose efficacy and material compatibility with endoscopes and endoscopic accessories has been tested and approved.

- *See section 1.3* ***"Chemicals for reprocessing"***
  Concentration and immersion times of the cleaning agent and disinfectant used should be taken from the information provided by the chemical manufacturer.

Do not use care products as these products leave behind deposits on the instruments and may damage the plastic material.

The approved cleaning agents and disinfectants must be compatible with each other.

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

☞ ***IMPORTANT!***

Do not use metal brushes for manual cleaning.

☞ ***IMPORTANT!***

When using a cleaning gun, ensure that the irrigation pressure is maximum 3 bar (43.5 psi).

☞ ***NOTE!***

To avoid perforations of the plastic outer sleeve, never grasp a flexible endoscope with an instrument holding forceps.

Only remove the flexible endoscope by hand from the certified cleaning agent/disinfectant solution.

6.2 Auxiliary resources required

- ◇ Leakage tester (163.903)
- ◇ Adapter (163914)
- ◇ Cleaning gun
- ◇ Cleaning brushes
- ◇ Sterile lint-free disposable cloth and cotton swab
- ◇ Storage systems
  - We recommend using the RIWO BOX (See section 11).
- ◇ Certified cleaning agent and disinfectant solution
- ◇ Conventional 20 ml syringe
- ◇ Tap water and sterile water

6.3 Manual leakage test

☞ ***IMPORTANT!***

Carry out the manual leakage test under dry conditions.
Failure to observe may result in humidity entering the flexible endoscope causing damage.

◇ Connect the tube part [via twist-lock (c)] to the pressure gauge.

Fig. 17

◇ Attach leakage tester (163.903) at the instrument-side connector for the leakage test and pressure equalization (9).
  ◗ Install the locking collar (c) against the connector for leakage test and pressure equalization (9) as far as it will go and secure by engaging the twist-lock.
◇ Close the knurled screw (d).
◇ Pump up the flexible endoscope with the rubber bulb until the indicator is in the green area (100 - 200 mmHg).
  ◗ An initial pressure drop is caused by the expansion of the elastic tubes / hoses.
  ◗ The flexible endoscope leaks if the pressure drops within 30 seconds.
  In this case please return the flexible endoscope to RICHARD WOLF for repair.
  If the pressure reading is constant, the flexible endoscope is leak-tight.
◇ The pressure is released by opening the knurled screw (d).

☞ ***IMPORTANT!***

After opening the knurled screw (d) wait at least 20 seconds before you remove the leakage tester. This guarantees complete pressure equalization.

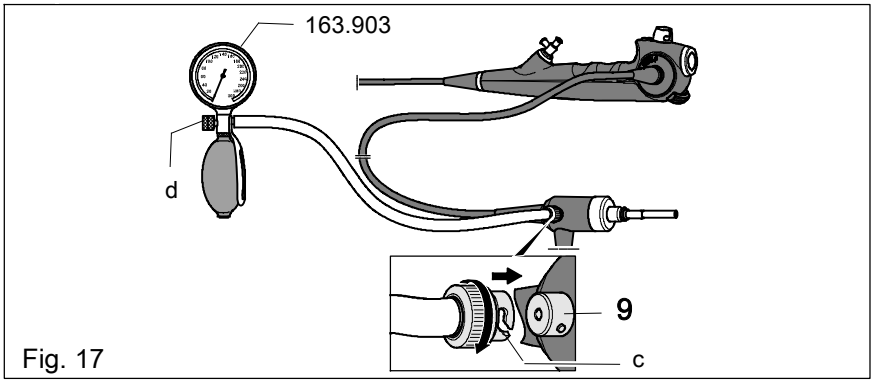


Fig. 17

☞ ***IMPORTANT!***

In the case of leakage (i.e. proven perforation) ***do not continue to reprocess*** *the flexible endoscope to prevent extension of the damage.*
Carefully wipe the outside of the flexible endoscope with a disposable cloth soaked with cleaning and disinfectant solution. Blow through the channels with compressed air and dry.
  ◗ *Follow the staff protection measures.*
Remove the foil included with the packaging system from the foil bag and place the flexible endoscope in the transit case as described in the accompanying document SF-015 for dispatch.

◇ Immediately after carrying out the leakage test, remove the tube connector [using the twist lock (a)] from the manometer.
◇ Spray the manometer and rubber bulb with surface disinfectant and wipe down with a lint-free disposable cloth.
◇ Reprocess the tube connector and the twist-lock mechanism.
  ◗ See section 1.10 **“Overview of reprocessing / material compatibility”.**

6.4 Manual cleaning

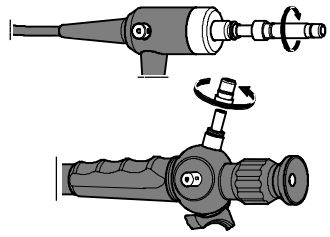


Fig. 18

Fig. 18

◇ Remove adapter from the projector and endoscope side and place in a small parts sieve or utensils basket.

6.4.1 Install adapter (163914) (only for 2-channel continuous irrigation laser URS)

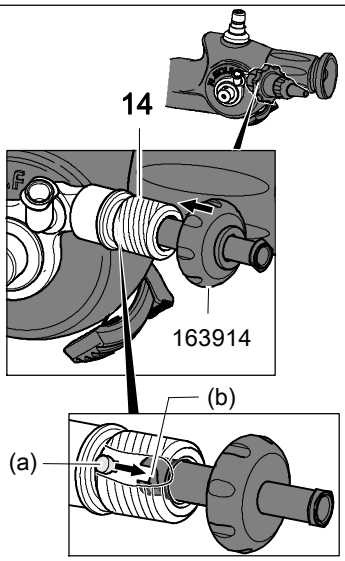


Fig. 19

Fig. 19

◇ Introduce the adapter (163914) in the receptacle for the laser adjustment unit (14).
  ◗ Pin (a) must engage in groove (b).

◇ Lock the adapter (163914) with the twist-lock mechanism.

6.4.2 Working channel (1) / suction channel (7) / laser fiber channel (13)

Fig. 20

◇ To remove any clogging and residues, rinse out channels using a 20 ml syringe filled with certified cleaning solution:

- Suction channel (7) through valve holder (6) - *(repeat 5x)*
- Working channel (1) through luer connector (2) - *(repeat 5x)*

Working channel (1) with irrigation connector configured below 45° (see Fig. 21)

- Rinsing connector (c) - *(repeat 1x)*
- Working channel (1) - *(repeat 4x)*
  Close the irrigation connector (c) with a finger.

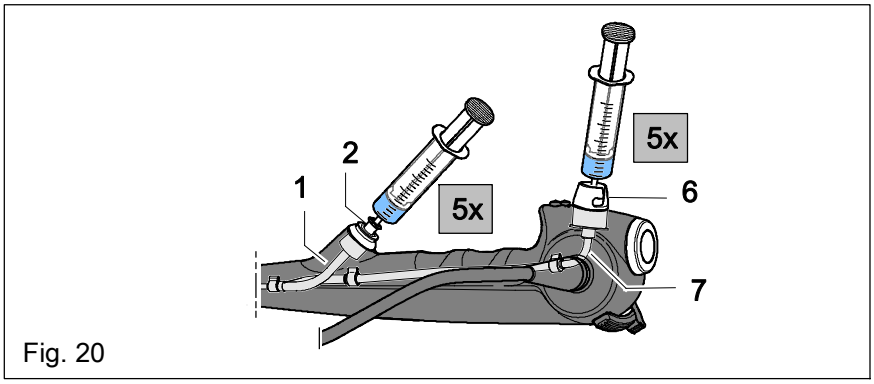


Fig. 20

Fig. 21

Only for 2-channel continuous irrigation laser URS

- Rinsing connector (c) - *(repeat 1x)*
- Working channel (1) - *(repeat 4x)*
  Close the irrigation connector (c) with a finger.
- Irrigation connector (d) - *(repeat 1x)*
- Laser fiber channel (13) through adapter (163914) - *(repeat 4x)*
  Close the irrigation connector (d) with a finger.

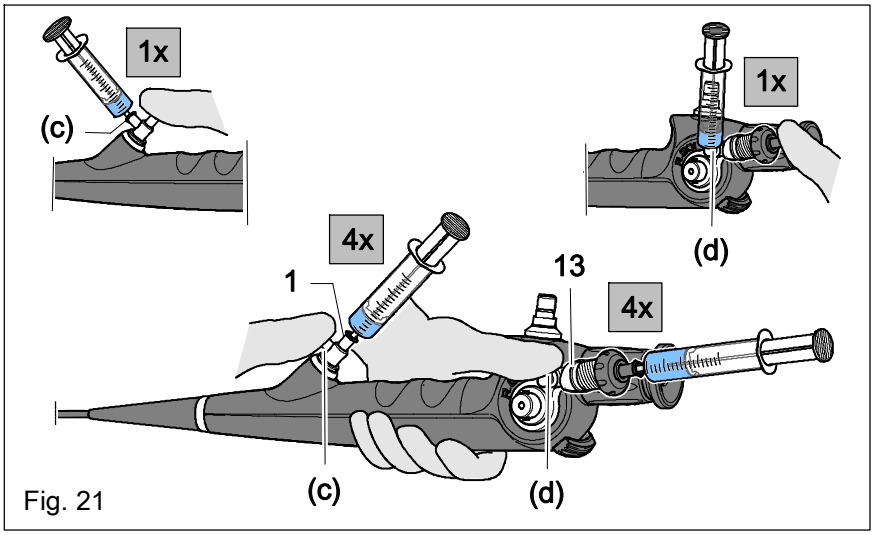
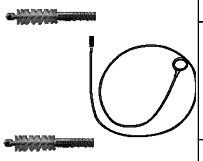
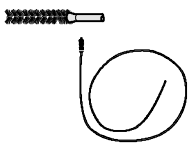


Fig. 21

6.4.3 Selecting the cleaning brushes

ILLUSTRATION	PRODUCT NO.	DESIGNATION	for cleaning: Working channel	Laser fiber channel	Suction channel	Valve element	Adapter	Biopsy valve
		MULTIPLE USE CLEANING BRUSHES						
	7264.691	**Cleaning brush** for fiberscopes, working channel dia. Ø 2 mm - 2.5 mm. Overall length 1000 mm, brush length 8 mm, brush head dia. Ø 3 mm	●	○	○	○	○	○
	7321.911	**Cleaning brush** for fiberscopes, working channel dia. Ø 1.1 mm - 2.0 mm. Overall length 1000 mm, brush length 10 mm, brush head dia. Ø 2.5 mm	●	○	○	○	○	○
	7326911	**Cleaning brush** for fiberscopes, working and laser fiber channel of Ø 1.0 mm - 1.5 mm Overall length 1200 mm, brush length 15 mm, brush head dia. Ø 2.2 mm	●	●	○	○	○	○
	7268.691	**Cleaning brush** For fiberscope accessories, e.g. stopcocks Overall length 285 mm, brush length 10 mm, brush head dia. Ø 5.0 mm	○	○	●	●	●	●
	86.90	**Cleaning brush** Steam-sterilizable universal brush						
		DISPOSABLE CLEANING BRUSH						
	7990001	**Disposable cleaning brush** for fiberscopes, working and laser fiber channel of Ø 1.0 mm - 1.5 mm Color: yellow Overall length 1200 mm, brush length 15 mm, brush head dia. Ø 2.0 mm, Packaging unit = Pack of 10.	●	●	○	○	○	○
	7990002	**Disposable cleaning brush** for fiberscopes, working channel dia. Ø 2.0 mm - 2.5 mm color: green Overall length 1200 mm, brush length 20 mm, brush head dia. Ø 3.0 mm, Packaging unit = Pack of 10.	●	○	○	○	○	○
	7990003	**Disposable cleaning brush** for fiberscope, laser fiber channel of Ø 0,8 mm, Color: blue Overall length 1200 mm, brush length 10 mm, brush head dia. Ø 0.85 mm, Packaging unit = Pack of 10.	○	●	○	○	○	○

Legend: ● = allowed ○ = not allowed

6.4.4 Biopsy valve (5) / suction valve (8) / laser adjustment unit, complete (15)

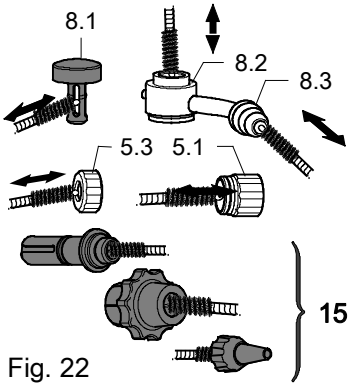


Fig. 22

Fig. 22

◇ Immerse the following parts in a certified cleaning solution and clean the outside with a lint-free disposable cloth or cotton swab.
- ◗ Valve housing (5.1), sealing cap (5.3)
- ◗ Valve tappet (8.1), valve insert (8.2), tube connector (8.3)
- ◗ Laser adjustment unit, complete (15)
- ◗ Follow the cleaning agent manufacturer's instructions.

◇ Then clean with a cleaning brush or carry out ultrasound cleaning.
- ◗ See section 6.4.3

◇ Rinse all parts with tap water and check for cleanliness.

◇ Dry using a lint-free disposable cloth or a cotton swab, dry openings and hollow spaces with compressed air.

6.4.5 Stopcocks (4.2)

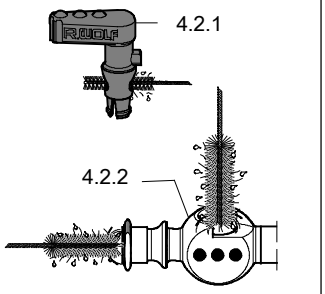


Fig. 23

Fig. 23

◇ Remove the stopcock plug (4.2.1).

◗ See product-specific instructions for use

◇ Clean with cleaning brush (see section 6.4.3):

◗ Stopcock plug (4.2.1)

◗ Stopcock housing (4.2.2)

6.4.6 Working channel (1) / suction channel (7) / laser fiber channel (13)

◇ Carefully clean channels with the corresponding cleaning brushes.

Adhere to the following sequence:

1. Clean the suction channel (7) via the valve holder (6)
2. Clean the working channel (1) via the luer connector (2)

Only for 2-channel continuous irrigation laser URS

3. Clean the laser fiber channel (13) via the receptacle for the laser adjustment unit (14)

☞ ***IMPORTANT!***

We recommend using the atraumatic cleaning brushes from RICHARD WOLF listed in the section 6.4.3 in order to avoid damage to the flexible endoscopes.

6.4.6.1 Disposable cleaning brushes

Fig. 24 / Fig. 25

☞ ***IMPORTANT!***

*When using **disposable cleaning brushes** for cleaning the working channel (1) / laser fiber channel (13) (see section 6.4.3)!*
Pass the cleaning brush with its brushless end only from proximal to distal through the working channel (1) / laser fiber channel (13) without exerting any force.
Only pass cleaning brush in the direction of the arrow, as shown in Fig. 24 and Fig. 25, pull completely through the working channel (1) / laser fiber channel (13) - (repeat 5x).

☞ ***IMPORTANT!***

*Do **not** pull the cleaning brush back and forth in the working channel (1) / laser fiber channel (13) as this can cause damage.*

Working channel (1)

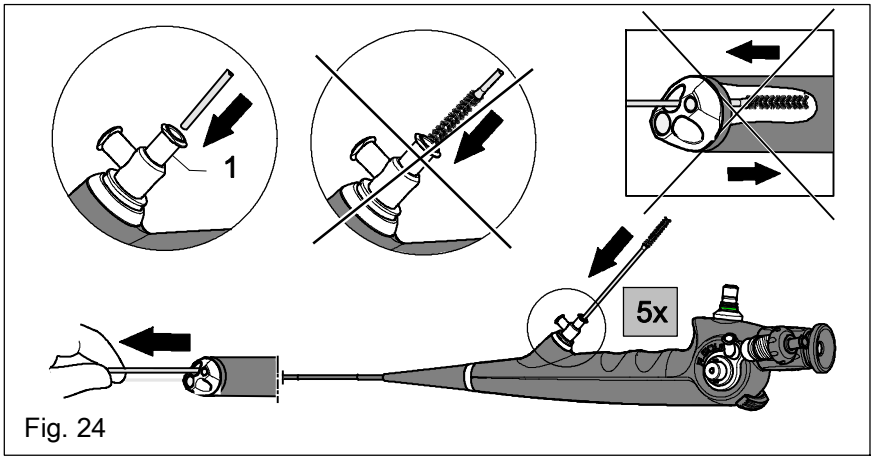


Fig. 24

Laser fiber channel (13)

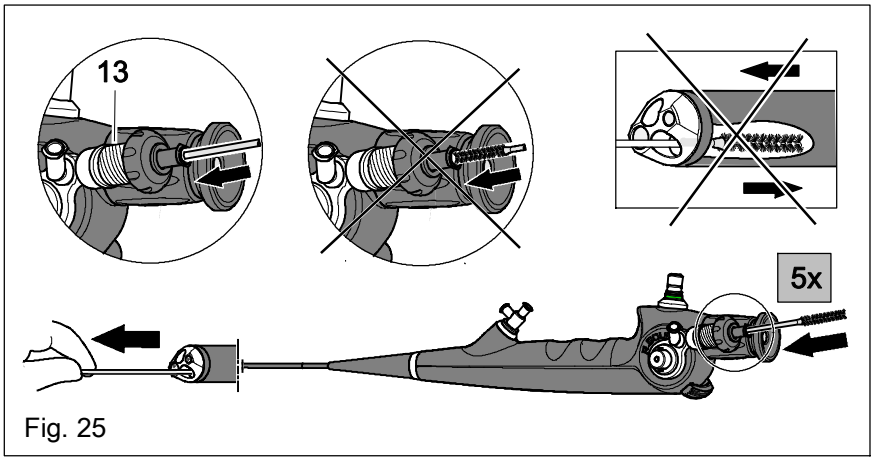


Fig. 25

6.4.6.2 Reprocessable cleaning brushes

Fig. 26 / Fig. 27

☞ ***IMPORTANT!***

*When using **multiple-use cleaning brush** for cleaning the suction channel (7) (see section6.4.3)!*
As shown in Fig. 26, insert the cleaning brush as far as it will go in the valve holder (6) without using any force.
Draw the cleaning brush back and forth in the suction channel (7) - (repeat 5x).

☞ ***IMPORTANT!***

*When using **multiple-use cleaning brushes** for cleaning the working channel (1) / laser fiber channel (13) (see section 6.4.3)!*
Insert the cleaning brush into the working channel (1) / laser fiber channel (13) only from proximal to distal.
Only pass cleaning brush through the working channel (1) / laser fiber channel (13) as shown in Fig. 27 and only pull back when the brush head has projected at the distal end - (repeat 5x).

☞ ***IMPORTANT!***

*Do **not** pull the cleaning brush back and forth in the working channel (1) / laser fiber channel (13) as this can cause damage.*

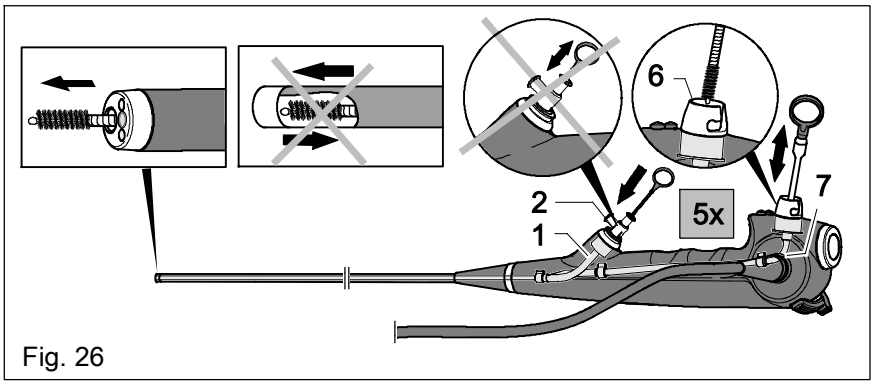


Fig. 26

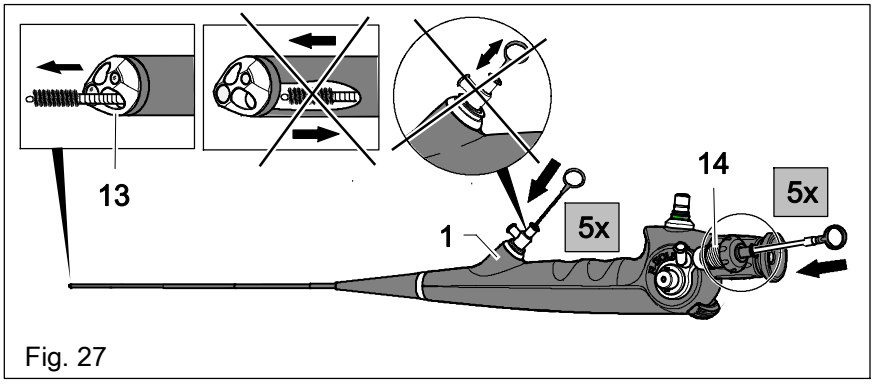


Fig. 27

◇ Rinse through inside and rinse off outside of flexible endoscope with a certified cleaning solution in order to remove all released particles.
◇ Reprocess cleaning brushes.
➧ See section 1.10 **"Overview of reprocessing / Material compatibility"**.

Fig. 28

◇ Clean with cleaning brush 86.90:

- Valve holder (6)
- Luer connector (2)
- Receptacle for laser adjustment unit (14)

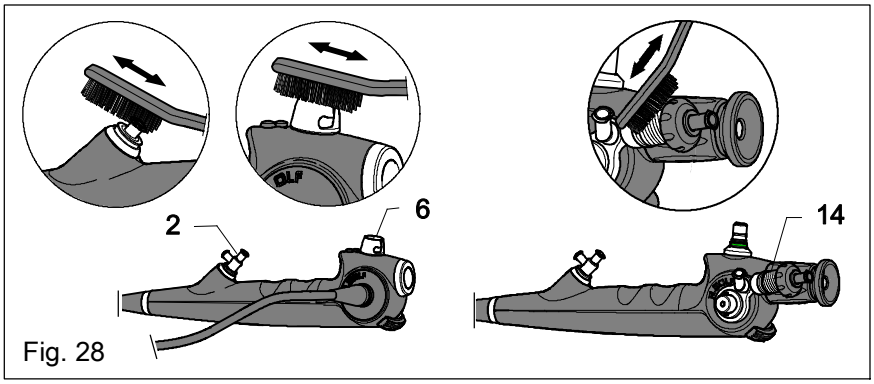


Fig. 28

◇ Immerse flexible endoscope in a RIWO BOX filled with water (“Water quality” see section 3) and rinse through all channels in order to completely remove the cleaning solution.

- Same procedure as described under section 6.4.2.

Fig. 29

◇ Then dry all the channels (1) (7) (13) until there is no more egress of moisture:

- with pressure-reduced, filtered compressed air or
- with special air pumps or
- with 20 ml syringe
- rinse through with 70% sterile alcohol

◇ Dry the outside with lint-free disposable cloth or cotton swab.

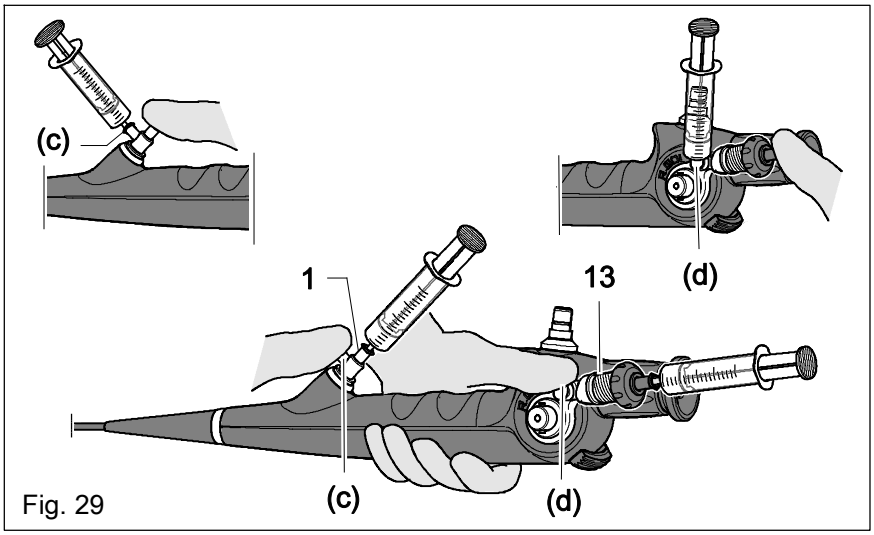


Fig. 29

6.5 Manual disinfection

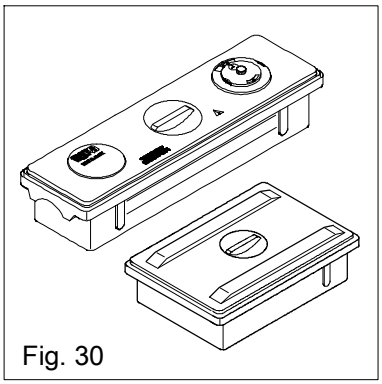


Fig. 30

Fig. 30

◇ For manual disinfection we recommend our RIWO BOX system.
This system features the following advantages:
◗ The sieve basket can be placed onto the integrated support points in such a way that the liquid dripping off flows back into the container.

◇ Immerse flexible endoscope in a certified disinfectant solution.
Observe the information provided by the disinfectant manufacturer
◗ Disinfection efficacy
◗ Concentration
◗ Immersion time and
◗ Use life

◇ In order to avoid mechanical damage, immerse the flexible endoscope and the accessories separately for each other in the certified disinfectant solution.

Fig. 31

◇ Immerse flexible endoscope in a RIWO BOX filled with certified disinfectant and rise through all channels.
◗ Same procedure as described under section 6.4.2.

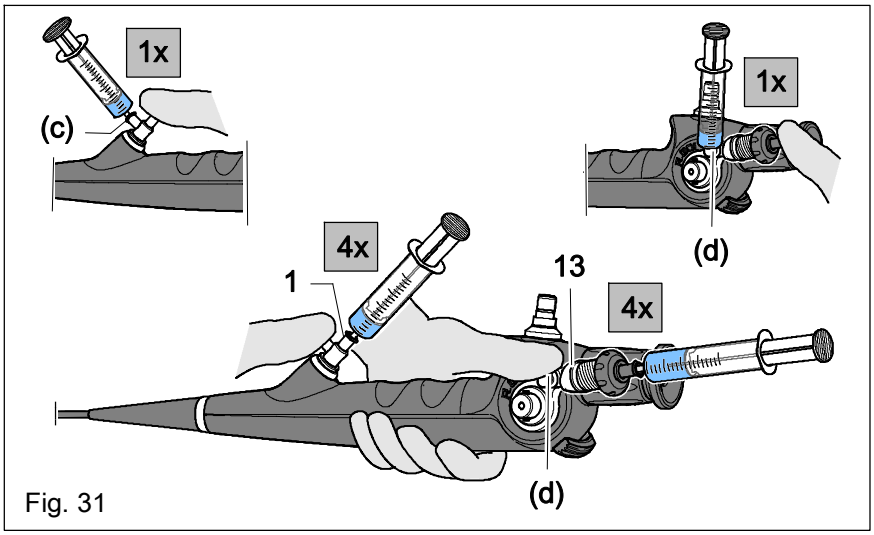


Fig. 31

◇ Use a 20 ml syringe to fill all channels with a certified disinfectant solution.
◇ Cover the RIWO BOX with an appropriate cover during disinfection.

6.5.1 After disinfection

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

◇ Rinse the following with sterile water:
  ◗ Rinse out all channels with a disposable syringe until the liquid running out is clear.
  ◗ Biopsy valve (5) and suction valve (8).
◇ Dry all channels until the air coming out is dry:
  ◗ with pressure-reduced, filtered compressed air or
  ◗ with special air pumps or
  ◗ with disposable syringe
◇ Remove adapter (163914).
◇ Dry flexible endoscopes on the outside with a sterile lint-free disposable cloth or a cotton swab.

☞ ***NOTE!***
In order to improve drying, the working channel (1), the suction channel (7) and the laser fiber channel (13) can be rinsed out with sterile 70% alcohol (ethanol, isopropanol) before drying.

☞ ***IMPORTANT!***
If flexible endoscopes are not dried adequately, microorganisms may multiply in the residual moisture during storage, e.g. in the channel system of the endoscope and may constitute a source of infection for patients examined at a later date.
The flexible endoscopes therefore need to be dried completely.

6.6 Storage systems

◇ The RIWO System Trays and RIWO BOXES can be cleaned with a certified cleaning solution, e.g. enzymatic cleaning agent.
◇ After cleaning has been carried out, rinse all parts with tap water and carefully dry with a lint-free disposable cloth.

7 Checks and maintenance

⚠ *CAUTION!*
Be careful if products are damaged or incomplete!
Injuries of the patient, user and others are possible.
Run through the checks before and after each use.
Do not use the products if they are damaged, incomplete or have loose parts.
Return damaged products together with any loose parts for repair.
Do not attempt to do any repairs yourself.

7.1 Visual check

◇ Check the flexible endoscope, in particular its distal area and the accessories, for:
- Damage
- Sharp edges
- Loose or missing parts
- Rough surfaces

◇ Any inscriptions or identification necessary for the safe intended use must be legible.
- Missing, illegible inscriptions and identifications leading to wrong handling and reprocessing must be reinstated.

◇ Check for perfect condition and replace if necessary:
- Sealing valve (5.2)
- Sealing membrane (8.4)
- Fastening element (15.1)

7.2 Function check

◇ Check for free passage (patency):
- Working channel (1)
- Suction channel (7)
- Supply, drain and insertion stopcock (4.1)
- Laser fiber channel (13) [only for 2-channel continuous-irrigation laser URS]

◇ Check opening and closing of inlet, outlet and instrument port stopcock (4.1).

◇ Check for secure connections.

◇ Check image quality and light output in conjunction with the system components.

◗ See product-specific instructions for use

Fig. 32

◇ Check glass surfaces for deposits.

◗ Deposits on the glass surfaces can cause a spotted or blurred field of view and hence impair light transmission considerably.

◗ Clean glass surfaces with a cotton swab soaked in alcohol (wooden swab carrier, not metal or plastic), as necessary clean off hard-to-remove deposits with a suitable instrument cleaner.

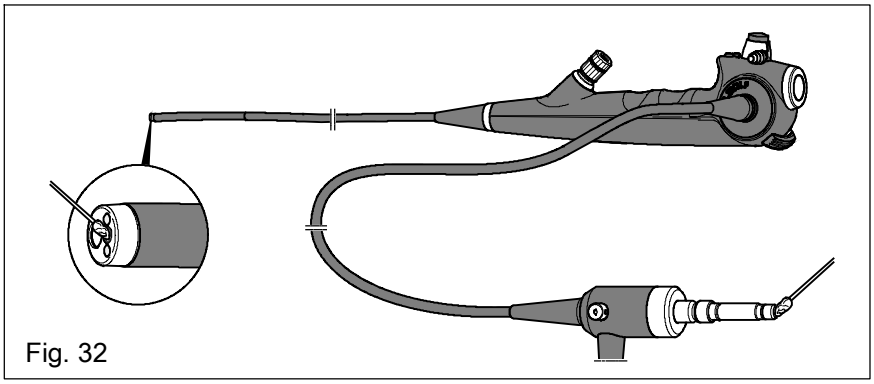


Fig. 32

◇ Check light output without the system components.

Fig. 33

◇ Direct the distal end of the flexible endoscope towards a light source.

◗ Broken fibers appear as black dots at the cold-light connector. If approx. 30% of the fibers are broken, the light output is no longer sufficient.

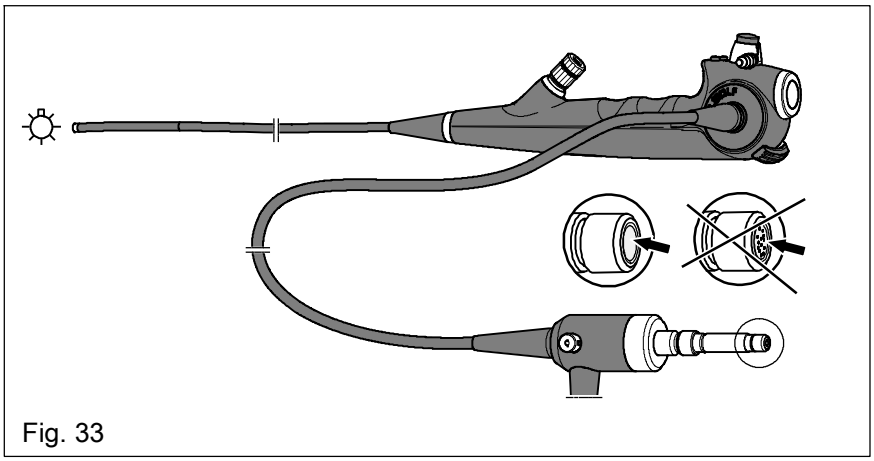


Fig. 33

☞ ***IMPORTANT!***

If deposits cannot be removed, return the flexible endoscope for repair.

☞ ***IMPORTANT!***

Regular cleaning with alcohol after reprocessing prevents deposits.

8 Sterilization

⚠ *CAUTION!*
High thermal load!
Temperatures above 60°C and steam and hot-air sterilization are not permissible!
Use only a low-temperature procedure to sterilize flexible endoscopes in order to avoid damage.

☞ *IMPORTANT!*
The instructions provided in section 1.10 ***"Overview of reprocessing / material compatibility"*** *were approved by RICHARD WOLF for preparation of a medical device for purposes of reuse.*
It is the responsibility of the reprocessor to make sure that the reprocessing actually carried out comprising the equipment, materials and personnel achieves the required results in the reprocessing unit.
This requires validations and routine monitoring of the procedures. Any deviation from the instructions provided should be carefully evaluated by the reprocessor for efficacy and possible unfavorable results.

☞ *NOTE!*
Depending on the product version, the following parts can optionally also be steam-sterilized at 134°C (273°F) using the fractional pre-vacuum method.
- *Suction valve (8) / new sealing membrane (8.4)*
- *Biopsy valve (5) / new sealing valve (5.2)*
- *Laser adjustment unit (14) / new fastening element (15.1)*
  [only 2-channel continuous irrigation laser URS]
- *Adapter (4) / stopcock plug (4.2.1)*

Sterilize all parts in assembled condition.
- *Immerse untensioned sealing membrane (8.4)*

8.1 Auxiliary resources required

◇ Connector for leakage test and pressure equalization (9)
◇ Lint-free disposable cloth and cotton swab
◇ Storage systems, e.g.
- RIWO System Tray
- Sterisafe® DURO A3 Set for H_2O_2 fiberscopes with disposable filter for H_2O_2

◇ Recommendation: e.g. LTSF valve (WEBECO)
◇ Standard packaging

8.1.1 Sterisafe® DURO A3 Set for fiberscopes H_2O_2

Fig. 34

◇ We recommend the Sterisafe® DURO A3 Set for the low temperature sterilization procedure with hydrogen peroxide H_2O_2 and gas [ethylene oxide (EO) and low temperature steam and formaldehyde (LTSF)], and for sterile storage and for transport.

◗ Particularly in the case of sterilization procedures with hydrogen peroxide H_2O_2 the material compatibility of the flexible endoscope is positively influenced by the use of Sterisafe®.

Fig. 34

8.2 Low-temperature sterilization

Use the low temperature sterilization procedure only for material to be sterilized which cannot be sterilized using the steam sterilization process due to its heat sensitivity.

- ◇ The instruments must be sufficiently dry for sterilization.
- ◇ Open inlet, outlet and instrument port stopcock (4.1) (see Fig. 5 on page 9).
- ◇ Do not expose flexible endoscopes to sudden temperature changes.
- ◇ The container with the flexible endoscopes must be allowed to cool - slowly - to hand heat in the sterilizer.
- ◇ Follow the instructions / manual of the sterilizer manufacturer.

☞ ***IMPORTANT!***

RICHARD WOLF has checked and validated the reprocessing procedures described below with regard to their material compatibility.

These procedures have been approved for use in conjunction with flexible endoscopes and endoscopic accessories with certain limitations – see the corresponding notes and instructions.

- ◗ *Flexible endoscopes by RICHARD WOLF were validated with the STERRAD® 50 / 200 / 100S / NX™ and 100NX™ sterilization procedures with regard to their efficacy.*

☞ ***IMPORTANT!***

Under no circumstances should the low temperature sterilization procedure with hydrogen peroxide (section 8.2.2 / 8.2.4.3) and the procedure with peracetic acid (section 8.2.5) be used alternatingly.

The interaction between these sterilization procedures can cause damage to the instruments.

☞ ***NOTE!***

All channels must be open.

Follow the sterilizer manufacturer's instructions.

8.2.1 Install pressure equalization valve (A) or LTSF valve (B)

☞ ***IMPORTANT!***

For the low-temperature sterilization procedure using hydrogen peroxide plasma and gas (section 8.2.2 / 8.2.4), the pressure equalization valve (A) must be installed on the connector for leakage test and pressure equalization (9).

For the low-temperature sterilization procedure using low-temperature steam and formaldehyde (LTSF), we recommend using the LTSF valve (B) with a specific adapter on the connector for leakage test and pressure equalization (9).

Advantage of the LTSF valve (B) with two anti-parallel non-return valves:

- *A valve permits evacuation to an internal residual pressure of approximately 300 mbar / 4.35 psi (rel.) in order to avoid damage from internal overpressure.*
- *The second valve only opens during ventilation at the end of the process when there is an external overpressure of approx. 200 mbar / 2.90 psi (rel.). This ensures that both paths are always closed in process phases where steam or formaldehyde is present in the sterilization chamber [50 - 200 mbar (abs.) / 0.73 – 2.90 psi (abs)].*

☞ ***IMPORTANT!***

All connectors must be dry.

Fig. 35

◇ Attach pressure equalization valve (A) or LTSF valve (B) at the connector for leakage test and pressure equalization (9).

- Install the pressure equalization valve (A) or the specific adapter of the LTSF valve (B) as far as it will go for the leakage test and pressure equalization (9) and lock using the twist lock.

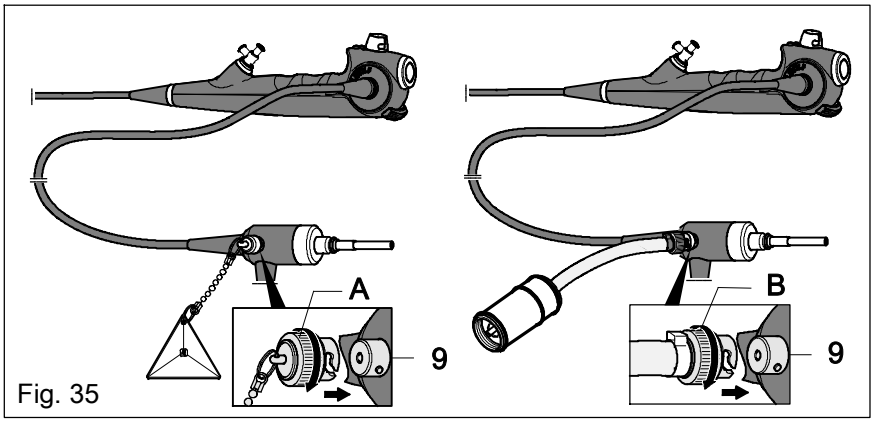


Fig. 35

☞ ***IMPORTANT!***

The valves (A) and (B) can only be used during the following low temperature sterilization procedure:

- *Pressure equalization valve (A) = H_2O_2 and EO*
- *LTSF valve (B) = LTSF*

When the pressure equalization valve or LTSF valve (B) is screwed on, fluid might penetrate the interior of the flexible endoscope during cleaning or during immersion and destroy the interior components.

Remove the pressure equalization valve (A) or the LTSF valve (B) before use.

8.2.2 Hydrogen peroxide plasma

☞ ***NOTE!***

With various materials such as black anodized aluminum or plastic materials, severe discolorations can occur. This however does not imply functional impairment.

8.2.2.1 STERRAD® 50 / 100S / 200 / NX™ and 100 NX™

Sterilization validations have been carried out on different products in cooperation with **"ASP"** (**A**dvanced **S**terilization **P**roducts) and the **"Martin Luther University Halle Wittenberg"**.

☞ ***NOTE!***

*STERRAD® compatible medical products are listed in the **"ASP Sterility Guide"**.*

www.sterradsterilityguide.com

8.2.3 Sterilization using a booster / diffusion amplifier in STERRAD® 50 / 100S / 200

Fig. 36 / Fig. 37

☞ ***IMPORTANT!***

*When using a booster, **never** plug it onto the distal end of the fiberscope, as the direct contact with the concentrated hydrogen peroxide will damage the plastic tube and the adhesive.*

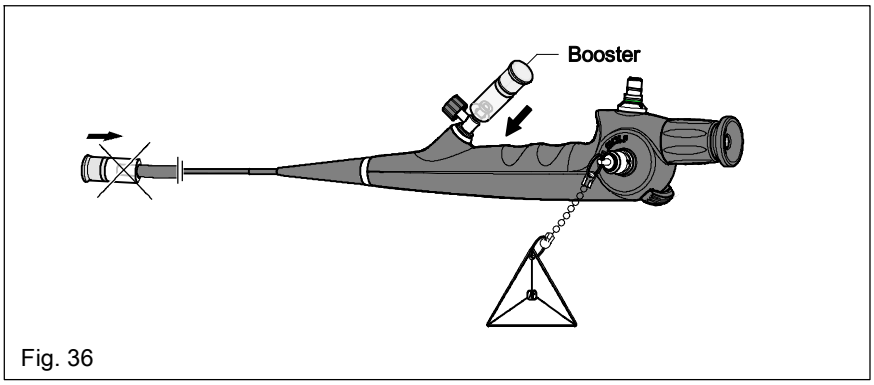


Fig. 36

Only for 2-channel continuous irrigation laser URS

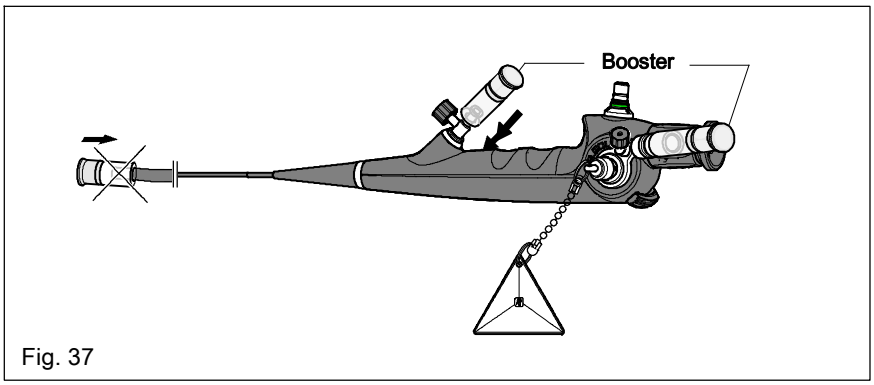


Fig. 37

8.2.4 Gas

8.2.4.1 Ethylene oxide gas (EO)

◇ Allow instruments to ventilate.

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. The maximum limit value is defined in ISO 10993 part 7 and must be followed.

Desorption depends on a multitude of factors, such as:

- Type of sterilization procedure (EO 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 30°C to 60°C (86°F - 140°F), a ventilation (desorption) time of some hours is usually sufficient. At room temperature desorption usually takes several days.

Sterilizability of RICHARD WOLF heat-sensitive instruments using ethylene oxide gas has been proven under the following conditions:

◗ Sterilization temperature:	40°C ± 3°C (104°F ± 5.4°F)
◗ Pre-vacuum:	>110 mbar ± 10 mbar (>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:	750 mbar ± 30 mbar absolute (10.9 psi± 0.45 psi absolute)
◗ N_2 buffer:	150 mbar ± 10 mbar (2.2 psi± 0.15 psi)
◗ Number of N_2 purging cycles:	2
◗ Number of air purging cycles:	4

☞ ***IMPORTANT!***

According to manufacturer's specifications, ethylene oxide 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:	32 - 35°C (89.6°F - 95°F)
◗ Air circulation:	10 times per hour
◗ Air exchange:	once per hour
◗ Desorption time:	6 hours

8.2.4.2 Low-temperature steam and formaldehyde (LTSF)

Sterilization with low temperature steam and formaldehyde (LTSF) is an alternative to sterilization with ethylene oxide gas. Compared to the ethylene oxide procedure, the FA procedure offers a number of advantages.

The formaldehyde water vapor mixture is neither flammable nor explosive. After the process of the sterilization cycle has been completed, this mixture is removed from the products so that they are reusable without further ventilation (desorption) time.

Sterilizability with low temperature steam and formaldehyde (LTSF) has been carried out and validated in conformity with EN 14180 / DIN EN ISO 25424 under the following conditions:

◗ Sterilization temperature:	60 °C + 4 °C (140 °F + 7.2 °F)
◗ Fractional pre-vacuum:	15-fold pressure change between 50 and 218 mbar (0.73 and 3.2 psi)
◗ Exposure time:	60 minutes
◗ Formaldehyde concentration:	2%
◗ Chamber volume:	135 liters
◗ Fractional steam cleaning:	20 times

8.2.4.3 Hydrogen peroxide (V-PRO™1)

Another alternative procedure is gas sterilization using hydrogen peroxide. For this procedure

◇ material compatibility was tested

◇ efficacy was verified.

◗ Follow information provided by the sterilizer manufacturers.

◗ Additional information is available on request

8.2.5 Peracetic acid

8.2.5.1 STERIS SYSTEM 1® / STERIS SYSTEM 1E™

The STERIS SYSTEM 1® / STERIS SYSTEM 1E™ sterilization procedure uses peracetic acid in conjunction with corrosion inhibitors. If used as intended, corrosion can be excluded.

These sterilization procedures are **"Just-in-time"** procedures.

☞ ***IMPORTANT!***

The pressure equalization valve (A) or LTSF valve (B) must not be used with the STERIS SYSTEM 1® / STERIS SYSTEM 1E™ sterilization procedure!

When the pressure equalization valve (A) or LTSF valve (B) is screwed on, fluid might penetrate the interior of the flexible endoscope during the STERIS SYSTEM 1® / STERIS SYSTEM 1E™ sterilization procedure and destroy the interior components.

The pressure equalization valve (A) should only be used during the low temperature sterilization procedure, H_2O_2 and ethylene oxide, the LTSF valve (B) should only be used during the low temperature sterilization procedure, low temperature steam and formaldehyde (LTSF)!

☞ ***NOTE!***

Connect instrument channels to the system so that all lumens are fully accessible by the reprocessing medium.

◗ *Follow the sterilizer manufacturer's instructions.*

8.3 Sterilization of storage systems and cleaning accessories

8.3.1 RIWO System Tray and Sterisafe® DURO A3 Set

◇ RIWO System Trays and Sterisafe® DURO A3 Set do not need separate sterilization. Sterilization takes place together with the flexible endoscope stored in the tray.

8.3.2 Cleaning brushes and cleaning wire

Multiple use cleaning brushes and cleaning wire can be steam sterilized with a fractional pre-vacuum method at 134°C (273° F).

☞ *IMPORTANT!*

Disposable cleaning brushes are intended for single use and must be disposed of after use in accordance with the country-specific guidelines and regulations.

9 Storage

☞ *IMPORTANT!*

Do not store flexible endoscopes in the transport case!

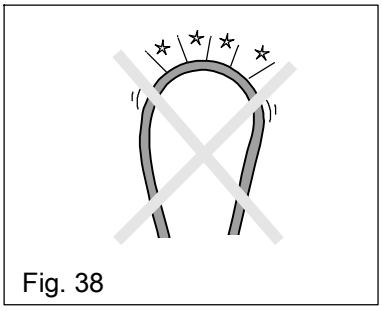


Fig. 38

Fig. 38

⚠ *CAUTION!*

Flexible endoscopes have limited strength!

Applying excessive force and high mechanical loads can cause damage (e.g. parting of cable / light cable) and impair the function.

Do not kink the flexible endoscope sheath and do not bend to excessively small radii (minimum diameter 150 mm).

9.1 After disinfection

◇ Store / keep the flexible endoscope under the following conditions:

- Completely dry
- Protected from dust
- In a closed drawer / container
- Under low microbial conditions
- Not in its transport case

9.2 After sterilization

◇ Store the flexible endoscope in its sterile packaging/wrapping as follows:

- Protected from humidity and changes in temperature
- Protected from direct solar radiation
- Protected from dust
- Preferably in a closed cabinet or a closed drawer / container

10 Repairs, returned products

⚠ *CAUTION!*

Risk of microbial carry-over!

In order to protect service personnel and to ensure safety during transport, we want to point out that any products returned for repair must be reprocessed hygienically by the sender according to the state-of-the-art prior to shipment.

If the products to be repaired are visibly soiled or contaminated, we reserve the right to charge the sender for reprocessing.

☞ *IMPORTANT!*

In the case of leakage (i.e. proven perforation) ***do not continue to reprocess*** *the flexible endoscope to prevent extension of the damage.*

Carefully wipe the outside of the flexible endoscope with a disposable cloth soaked in a certified cleaning disinfection agent. "Blow compressed air through the channels and dry".

- *Follow the staff protection measures.*

☞ *IMPORTANT!*

Return shipments to RICHARD WOLF

To avoid damage to the product as well as possible contamination of the transport case

- *Connect the pressure equalization valve (A) to the connector for leakage test and pressure equalization (9).*
- *Remove the foil included with the packaging system from the foil bag and place the flexible endoscope in the transit case as described in the accompanying document SF-015.*

11 Accessories for reprocessing

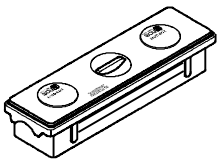
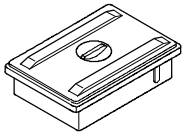
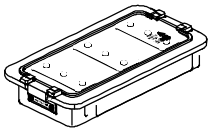
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		STORAGE SYSTEMS
	6860.911	**RIWO BOX** for wet decontamination of used and contaminated instrument set, not steam-sterilizable incl. sieve basket and lid Outside dimensions: 881 x 200 x 165 mm Inside dimensions of sieve basket: 760 x 150 x 100 mm
	509.81	**RIWO BOX** for disinfection, not steam-sterilizable incl. lid without sieve basket Outside dimensions: 600 x 400 x 140 mm Inside dimensions of basket: 548 x 348 x 100 mm
	38201.xxx	**RIWO System Tray** for sterilization on request
	8584.3003	**System basket for small parts 1/8** with lid L x W x H 121 x 121 x 35 mm
	382032000	**Sterisafe® DURO A3-Set for fiberscopes H_2O_2** STERRAD® / V-PRO™1 **consisting of:**
		382031003 Sterisafe® DURO A3 External dimensions (L x W x H) 450 x 292 x 87 mm Internal dimensions (L x W x H) 420 x 265 x 75 mm
		382031101 Toolsafe® grid mat
		382031401 Disposable filter H_2O_2 Pack of 100
	382032100	**Sterisafe® DURO A3 set for EO, LTSF** Ethylene oxide (EO) and low temperature steam and formaldehyde (LTSF) **consisting of:**
		382031003 Sterisafe® DURO A3 External dimensions (L x W x H) 450 x 292 x 87 mm Internal dimensions (L x W x H) 420 x 265 x 75 mm
		382031101 Toolsafe® grid mat
		382031501 Disposable filter EO and LTSF Pack of 100

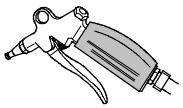
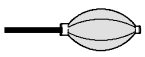
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		ACCESSORIES - STERISAFE® DURO A3
no illustration	382031401	**Disposable filter H_2O_2** Pack of 100
	382031501	**Disposable filters EO and LTSF** Pack of 100
	382031220	**Sealing label - H_2O_2** Pack of 500
	382031203	**Sterisafe® universal label holder**
	382031202	**Sterisafe® safety seal** Pack of 100
		CLEANING ACCESSORIES
	6199.00	**Cleaning gun** Water jet, for connecting to tap with R-3/4" thread incl. adapters (A - H, see below) and holder The adapters are suitable for cleaning the following
	15515.003	**A** Sheaths and inserts, syringes, injection cannulas
	15515.004	**B** Sheaths, measuring and blood pipettes
	15515.005	**C** Catheters
	15515.006	**D** Drainage hoses / tubes
	15515.007	**E** Stopcocks, cannulas, syringes
	15515.009	**F** Sprinkler adapters
	15515.008	**G** Bottles
	15515.010	**H** Water jet pumps (with adapters also suitable for drying)
		CLEANING ACCESSORIES
	103.00	**Rubber bulb** for blowing air through the channels
	127.00	**Double bulb with luer fitting 886.00** for blowing air through the channels

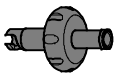
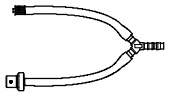
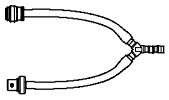
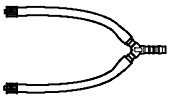
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		CONNECTION IN THE AWD DEVICE
	163.905	**Adapter** for leakage test, for use in Olympus washer-disinfectors
	15092.102	**Adapter, complete** for leakage test, for use in washer-disinfectors of other manufacturers
	163914	**Adapter** for cleaning the laser fiber channel with the flexible 2-channel continuous irrigation laser URS Diameter: approx. 20 mm
	-	**Cleaning adapter** for Olympus AWD device (device end) *is directly available from Miele (item no. 69744701)*
		RINSING SETS FOR MACHINE REPROCESSING
	163.907	**Rinsing set II** for flexible ◗ Bronchoscope ◗ DAFE Bronchoscope
	163.908	**Rinsing set III** for flexible ◗ Video Bronchoscope ◗ DAFE Video Bronchoscope ◗ LED Video Bronchoscope
	163910	**Rinsing set V** Double luer connector for T connector of the flexible ◗ Fiber Uretero-Renoscope ◗ Video Urethro-Cystoscope ◗ PDD Video Urethro-Cystoscope ◗ LED Video Urethro-Cystoscope ◗ 2-channel continuous irrigation laser URS (2 x rinsing set V) ◗ BOA Vision Flexible Sensor URS ◗ COBRA Vision Flexible Sensor URS (2 x rinsing set V) ◗ Attachment (and additional rinsing tube)

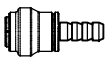
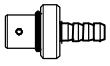
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		CONNECTORS - AS AN ALTERNATIVE TO RINSING SETS
Connectors / adapter		**ADAPTER**
3 x 886.00  3 x rinsing tube	**7305.782**	Adapter (4)
Connectors / Videoscope		**VIDEOSCOPES**
2 x 886.00  2 x rinsing tube	**7308.001**	Flexible Video Urethro-Cystoscope (PAL)
	7308.006	Flexible Video Urethro-Cystoscope (PAL)
	7308.061	Flexible Video Urethro-Cystoscope (NTSC)
	7308.066	Flexible Video Urethro-Cystoscope (NTSC)
15028.083 2 x 886.00  3 x rinsing tube	**7308.0014**	Flexible Video Urethro-Cystoscope (PAL)
	7308.0064	Flexible Video Urethro-Cystoscope (PAL)
	7308.0614	Flexible Video Urethro-Cystoscope (NTSC)
	7308.0664	Flexible Video Urethro-Cystoscope (NTSC)
	73090014	Flexible Video Urethro-Cystoscope (PDD)
	73090064	Flexible Video Urethro-Cystoscope (PDD)
	73090614	Flexible Video Urethro-Cystoscope (PDD)
	73090664	Flexible Video Urethro-Cystoscope
	731000144	LED Video Urethro-Cystoscope
	73100614	LED Video Urethro-Cystoscope
	73100664	LED Video Urethro-Cystoscope
	731100144	LED Video Urethro-Cystoscope
	73110064	LED Video Urethro-Cystoscope
15028.103  15028.083  2 x rinsing tube	**7210.001**	LED Video Bronchoscope
	7210.061	LED Video Bronchoscope
	7268.001	Flexible Video Bronchoscope (PAL)
	7268.061	Flexible Video Bronchoscope (NTSC)
	7269.001	DAFE Video Bronchoscope (PAL)
	7269.061	DAFE Video Bronchoscope (NTSC)
	7270.001	DAFE Video Bronchoscope (PAL)
	7270.061	DAFE Video Bronchoscope (NTSC)

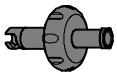
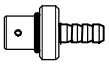
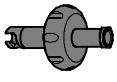
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		CONNECTORS - AS AN ALTERNATIVE TO RINSING SETS
Anschlussteile / Fiberskop		**SENSOR URS (VIDEOSCOPES)**
2 x 886.00  2 x rinsing tube	**7355071**	BOA Vision Flexible Sensor URS
	7355076	BOA Vision Flexible Sensor URS
163914 3 x 886.00   4 x rinsing tube	**7356071**	COBRA Vision Flexible Sensor URS
	7356076	COBRA Vision Flexible Sensor URS
Connectors / Fiberscope		**FIBERSCOPES**
2 x 886.00  2 x rinsing tube	**7325.071**	Flexible Fiber Urethro-Cystoscope
	7325.076	Flexible Fiber Urethro-Cystoscope
15028.083 **1 x 886.00**   2 x rinsing tube	**7265.001**	Flexible Bronchoscope
	7265.006	Flexible Bronchoscope
1 x 886.00  1 x rinsing tube	**7305.001**	Flexible Fiber Urethro-Cystoscope
	7305.006	Flexible Fiber Urethro-Cystoscope
	7305.011	Flexible Hysteroscope
	7223.001	Flexible Naso-Pharyngo-Laryngoscope
	7325.122	Flexible Fiber Hysteroscope
	7325.152	Flexible Choledochoscope
	7325.172	Flexible Fiber Uretero-Renoscope
	7330.052	Flexible Choledochoscope
	7330.072	Flexible Fiber Uretero-Renoscope
3 x 886.00  3 x rinsing tube	**7331.001**	Flexible Fiber Uretero-Renoscope
163914 3 x 886.00   4 x rinsing tube	**7326071**	2-channel continuous-irrigation laser URS
	7326076	2-channel continuous-irrigation laser URS
no channel	**7224.001**	Flexible Naso-Pharyngoscope

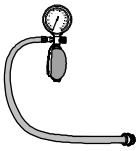
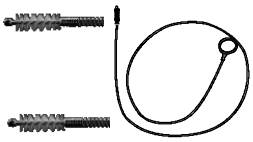
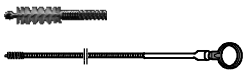
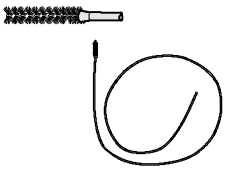
ILLUSTRATION	PRODUCT NO.	DESIGNATION
		SPARE PART AND ACCESSORIES
	896.0002	**Stopcock plug, complete** Passage 3.0 mm; Identification: 3 pegs Packaging unit = Pack of 5.
	38310.0001	**Disassembly tool**
		MANUAL LEAKAGE TEST
	163.903	**Leakage tester**
		VALVES FOR STERILIZATION
	163.904	**Pressure equalization valve (A)** for low temperature sterilization procedure with - Hydrogen peroxide H_2O_2 and - Gas [ethylene oxide (EO) and low temperature steam and formaldehyde (LTSF)
	-	**LTSF valve (B) Webeco** for formaldehyde sterilizer Webeco FA90/95 *Purchase directly from Webeco (product no. 045535)*
		MULTIPLE USE CLEANING BRUSHES
	7264.691	**Cleaning brush** for fiberscopes, working channel dia. Ø 2 mm - 2.5 mm Overall length 1000 mm, brush length 8 mm, brush head dia. Ø 3 mm
	7321.911	**Cleaning brush** for fiberscopes, working channel dia. Ø 1.1 mm - 2.0 mm Overall length 1000 mm, brush length 10 mm, brush head dia. Ø 2.5 mm
	7326911	**Cleaning brush** for fiberscopes, working channel dia. Ø 1.0 mm - 1.5 mm Overall length 1200 mm, brush length 15 mm, brush head dia. Ø 2.2 mm
	7268.691	**Cleaning brush** for fiberscope accessories, e.g. stopcocks Overall length 285 mm, brush length 10 mm, brush head dia. Ø 5.0 mm
	86.90	**Cleaning brush** Steam-sterilizable universal brush

ILLUSTRATION	PRODUCT NO.	DESIGNATION
		DISPOSABLE CLEANING BRUSHES
	7990001	**Disposable cleaning brush** for fiberscopes, working and laser fiber channel dia. Ø 1.0 mm - 1.5 mm Color: yellow Overall length 1200 mm, brush length 15 mm, brush head dia. Ø 2.0 mm Packaging unit = Pack of 10.
	7990002	**Disposable cleaning brush** for fiberscopes, working channel dia. Ø 2.0 mm - 2.5 mm Color: green Overall length 1200 mm, brush length 20 mm, brush head dia. Ø 3.0 mm Packaging unit = Pack of 10.
	7990003	**Disposable cleaning brush** for fiberscopes, laser fiber channel dia. Ø .8 mm Color: blue Overall length 1200 mm, brush length 10 mm, brush head dia. Ø 0.85 mm Packaging unit = Pack of 10.
		CLEANING AND CARE PRODUCTS
	102.02	**Anti-fogging agent, sterile** Disposable pipette Alcohol-free, silicone-free, wax-free, pack of 10

12 Literature

☞ *IMPORTANT!*

We do not guarantee that this literature index is complete. The user is obligated to keep abreast of all new developments in this field.

◇ **Reprocessing of instruments (red brochure: 10th edition 2012)**
Reprocessing instruments maintaining their value
[Instrument Reprocessing (Red brochure: 10th edition 2012)
Reprocessing instruments to preserve their value as assets]

◇ **Manual of sterilization**
[Manual of sterilization]
3M Switzerland

◇ **Mfr. MMM**
Münchner Medizin Mechanik “Leitfaden für den Umgang mit Sterilisiergut"
[Guidelines for handling items to be sterilized - 8th revised edition]

◇ **DIN EN ISO 10993-1: 2010**
Biologische Beurteilung von Medizinprodukten
[Biological evaluation of medical products]

◇ **DIN EN ISO 11607, part 1: 2009, part 2: 2006**
Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte
Packaging for terminally sterilized medical devices]

◇ **DIN EN ISO 15883, part 1-2: 2006; part 4: 2009**
Reinigungs-/ Desinfektionsgeräte - Anforderungen - Definitionen - Prüfmethoden
[Washer disinfectors - General requirements - Definitions - Test]

◇ **DIN EN ISO 17664: 2004**
Sterilisation von Medizinprodukten
Vom Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten
[Sterilization of medical devices:
Information to be provided by the manufacturer for the processing of resterilizable medical devices]

◇ **DIN EN ISO 17665-1: 2006**
Sterilisation von Produkten für die Gesundheitsfürsorge
[Sterilization of healthcare products]

◇ **ISO 11135**
Medizinische Geräte
Validierung und Routineüberwachung der Ethylenoxid-Sterilisation
[Medical devices
Validation and routine control of ethylene oxide sterilization]

◇ **ISO 13683**
Sterilisation von Produkten für die Gesundheitsfürsorge
Anforderungen an die Validierung und Routineüberwachung für die Sterilisation mit feuchter Hitze in Einrichtungen der Gesundheitsfürdorge
[Sterilization of healthcare products
Requirements for validation and routine control of moist heat sterilization in healthcare facilities]

◇ **ISO 14937**
Sterilisation von Medizinprodukten
Sterilisation von Produkten für die Gesundheitsfürsorge - Allgemeine Anforderungen an die Charakterisierung eines Sterilmittels und an die Entwicklung, Validierung und Routineüberwachung eines Sterilisationsverfahrens für Medizinprodukte
[Sterilization of medical devices
Sterilization of healthcare products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices]

◇ **DIN EN 285: 2006 + A2: 2009**
Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren
[Sterilization - Steam sterilizers - Large sterilizers]

◇ **DIN EN 550**
Sterilisation von Medizinprodukten
Validierung und Routineüberwachung für die Sterilisation mit Ethylenoxid
[Sterilization of medical devices
Validation and routine control of ethylene oxide sterilization]

◇ **DIN EN 554**
Sterilisation von Medizinprodukten
Validierung und Routineüberwachung für die Sterilisation mit feuchter Hitze
[Sterilization of medical devices
Validation and routine control of damp heat sterilization]

◇ **DIN EN 867, part 5**
Nichtbiologische Systeme für den Gebrauch in Sterilisatoren
[Non-biological systems for use in sterilizers]

◇ **DIN EN 868, parts 1 to 10**
(unterschiedliche Erscheinungsjahre der einzelnen Teile)
Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte
[(various parts published in different years)
Packaging materials and systems for medical products which are to be sterilized]

◇ **DIN EN 13060**
Dampf - Klein - Sterilisatoren
[Small steam sterilizers]

◇ **DIN EN 58946, part 6**
Sterilisation - Dampf - Sterilisatoren
[Sterilization - Steam sterilizers

◇ **DIN 58948, parts 6, 7, 16, 17**
Sterilisation - Niedertemperatur - Sterilisatoren
[Sterilization - Low-temperature sterilizers]

◇ **DIN 58952, parts 2, 3: 2012**
Sterilisation -Transportkörbe für Sterilbarrieresysteme
[Sterilization - Transport baskets for sterile barrier systems]

◇ **DIN 58953, parts 1, 6, 7 to 9**
(unterschiedliche Erscheinungsjahre der einzelnen Teile)
Sterilisations - Sterilgutversorgung
[(various parts published in different years)
sterilization - Sterile supply]

◇ **Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte**
Amtsblatt der Europäischen Gemeinschaften,
L 169, 36. Jahrgang, 12. Juli 1993
[Council Directive 93/42/EEC as of 14 June 1993 relating to medical devices Official Journal of the European Communities,
L 169, 36th volume, 12 July 1993]

Literature

◇ **UVV BGV A1 und Berufsgenossenschaftliche Regeln**
e.g. BGR 250, BGR 206 der Berufsgenossenschaft für Gesundheit und Wohlfahrtspflege
[Regulations e.g. 250, 206 of the Employers' Liability Insurance Association for (Private) Health and Welfare Services]

◇ **Desinfektionsmittel-Liste des VAH in der jeweils gültigen Fassung**
Liste der nach den Richtlinien für die Prüfung chemischer Desinktionsmittel geprüften und von der Deutschen Gesellschaft für Hygiene und Mikrobiologie als wirksam befundenen Desinfektionsverfahren (inkl. Verfahren zur Händedekontamination und hygienischen Händewaschung)
[Current version of the VAH list of disinfectants
List of disinfecting procedures tested in accordance with the guidelines for testing chemical disinfectants and considered effective by the German Society for Hygiene and Microbiology (including hand decontamination and hygienic hand-washing procedures).]

◇ **Liste der vom Robert-Koch-Institut geprüften und anerkannten Desinfektionmittel- und verfahren jeweils in der aktuellen Fassung**
[List of disinfectants and disinfecting methods tested and recognized by the Robert Koch Institute]

◇ **Europäische Pharmakopöe**
[European Pharmacopoeia]

◇ **Retouren in medizinischen Einrichtungen, Merkblatt, Handlungsempfehlungen, BV-Med, www.bvmd.de**
[Returned goods in medical institutions, fact sheet - Treatment Recommendations, BVMed, www.bvmd.de]

◇ **RKI (Robert-Koch-Institut)**
[RKI (Robert Koch Institute]

- Krankenhausversorgung und Instrumentensterilisation bei CJK-Patienten und CJK-Verdachtsfällen, Bundesgesundheitsblatt 7 (1998) 279-285
  [Hospital supplies and instrument sterilization in light of CJD patients and suspected CJD cases, Federal Health Gazette 7 (1998) 279-285]
- Anforderung an die Hygiene bei der Aufbereitung von Medizinprodukten. Bundesgesundheitsblatt 44 (2001) 1115-1126
  [Requirements for hygiene in the reprocessing of medical products, Federal Health Gazette 44 (2001) 1115-1126]
- Die Variante der Creutzfeldt-Jakob-Krankheit (vCJK)
  Bundesgesundheitsblatt 45 (2002) 376-394
  [The Creutzfeldt-Jakob disease variant (vCJD), Federal Health Gazette 45 (2002) 376-394]
- Anforderung an die Hygiene bei der Aufbereitung flexibler Endoskope und endoskopischen Zusatzinstrumenten, Bundesgesundheitsblatt 45 (2002) 395-411
  [Requirements for hygiene in the reprocessing of flexible endoscopes and endoscopic supplementary instruments, Federal Health Gazette 45 (2002) 395-411]
- Erläuterung zur Aufbereitung flexibler Zystoskope, Bundesgesundheitsblatt 43 (2005) 230-233
  [Commentary on reprocessing of flexible cystoscopes, Federal Health Gazette 43 (2005) 230-233]

◇ **ESGENA Richtlinien zur Reinigung und Desinfektion von GI-Endoskopen**
Protokoll für die Wiederaufbereitung von endoskopischem Zubehör
[ESGENA guidelines for cleaning and disinfection of GI endoscopes
Procedure for reprocessing of endoscopic accessories]

◇ **Bedeutung der Verordnung über die Qualität von Wasser für den menschlichen Gebrauch (TrinkwV2001) für die Krankenhaushygiene**
M.Exner - T.Kistemann - Universität Bonn, Bundesgesundheitsblatt 47 (2004) 384-391
[Significance of the directive on the quality of water for human consumption (TrinkwV2001) for hospital hygiene, Federal Health Gazette 47 (2004) 384-391]

◇ **Gesetz über Medizinprodukte (Medizinproduktegesetz - MPG) vom 13. Dezember 2001 (BGBl. I S. 3586)**
[Law on Medical Products]

◇ **Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung - MPBetreibV) vom 13. Dezember 2001 (BGBl. I S. 3586)**
[Directive on installing, operating and using medical products (Medical product operator directive) as of 13 December 2001, (Federal Gazette I p. 3586)]

◇ **ANSI/AAMI ST79: 2010 & A1: 2010 & A2: 2010**
Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. Association for the Advancement of Medical Instrumentation, 2010, 2011.

◇ **AAMI TIR12: 2010**
Designing, testing, and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for medical device manufactures. Association for the Advancement of Medical Instrumentation, 2010, 2011. Arlington, VA

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13 Index

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