

# Manual



**Reprocessing**  
of  
**RICHARD WOLF**  
Heat-Stable Instruments

GA-J020 / en / 2014-05 V17.0 / PDI 13-6891



**GERMANY**  
RICHARD WOLF GmbH  
75438 Knittlingen  
Pforzheimerstr. 32  
Telephone: +49 70 43 35-0  
Telefax: +49 70 43 35-4300  
**MANUFACTURER**  
info@richard-wolf.com  
www.richard-wolf.com

**BELGIUM / NETHERLANDS**  
N.V. Endoscopie  
RICHARD WOLF Belgium S.A.  
Industriezone Drongen  
Landegemstraat 6  
9031 Gent Drongen  
Telephone: +32 92 80 81 00  
Telefax: +32 92 82 92 16  
endoscopy@richard-wolf.be  
www.richard-wolf.be

**Marketing Office**  
**U.A.E**  
RICHARD WOLF Middle East  
P.O. Box 500283  
AL Thuraya Tower 1  
9<sup>th</sup> Floor,  
Room 904, Dubai  
Telephone: + 9 71 43 68 19 20  
Telefax: + 9 71 43 68 61 12  
middle.east@richard-wolf.com  
www.richard-wolf.com

**USA**  
RICHARD WOLF  
Medical Instruments Corporation  
353 Corporate Woods Parkway  
Vernon Hills, Illinois 60061  
Toll Free: 001 (800) 323 - 9653  
Phone: 001 (847) 913 - 1113  
Fax: 001 (847) 913 - 1488  
sales@richardwolfusa.com  
www.richardwolfusa.com

**FRANCE**  
RICHARD WOLF France S.A.R.L.  
Rue Daniel Berger  
Z.A.C. La Neuville  
F-51100 Reims  
Telephone: +33 3 26 87 02 89  
Telefax: +33 3 26 87 60 33  
france@richard-wolf.com

**INDIA**  
RICHARD WOLF India Private Ltd.  
JMD Pacific Square  
No. 211 A, Second Floor  
Behind 32<sup>nd</sup> Milestone  
Gurgaon - 122 001  
National Capitol Region  
Telephone: + 91 12 44 31 57 00  
Telefax: + 91 12 44 31 57 05  
india@richard-wolf.com  
www.richard-wolf.com

**UK**  
RICHARD WOLF UK Ltd.  
Waterside Way  
Wimbledon  
SW17 0HB  
Telephone: + 44 20 89 44 74 47  
Telefax: + 44 20 89 44 13 11  
admin@richardwolf.uk.com  
www.richardwolf.uk.com

**AUSTRIA**  
RICHARD WOLF Austria  
Ges.m.b.H.  
Wilhelminenstraße 93 a  
A-1160 Vienna  
Telephone: +43 14 05 51 51  
Telefax: +43 14 05 51 51 45  
austria@richard-wolf.com  
www.richard-wolf.com

## 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 upon 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
	<b>WARNING!</b> Failure to observe can result in death or extremely serious injuries.
	<b>CAUTION!</b> Failure to observe can result in slight injury or damage to the product.
	<b>IMPORTANT!</b> Failure to observe can result in damage to the product or surroundings.
	<b>NOTE!</b> User tips for optimum device use and other useful information.

# Contents

<b>1</b>	<b>General Information</b> .....	<b>1</b>
1.1	Manuals / Instructions for use .....	1
1.2	Material compatibility / proof of efficacy .....	1
1.3	Chemicals for reprocessing .....	1
1.4	Questions concerning RICHARD WOLF products .....	2
1.5	Basic notes and instructions .....	2
1.6	Brand new products .....	2
1.7	Disposable item .....	3
1.7.1	Unsterile disposable items .....	3
1.7.2	Sterile disposable items .....	3
1.8	Characteristic features of steam sterilizability .....	4
1.8.1	Telescopes and instruments .....	4
1.8.2	Objective lenses and camera heads .....	4
1.9	Instrument reprocessing .....	5
1.10	Overview of reprocessing / material compatibility .....	6
<b>2</b>	<b>Illustration</b> .....	<b>8</b>
<b>3</b>	<b>Water quality</b> .....	<b>10</b>
3.1	Ion exchanger for full demineralization .....	10
<b>4</b>	<b>Preparation of the instruments at the point of use</b> .....	<b>11</b>
4.1	Small-diameter instruments .....	11
4.2	HF instruments / electrodes .....	12
4.3	Reprocessable tube and hose systems .....	12
4.4	Transport .....	12
4.4.1	Dry preparation at the point of use .....	12
4.4.2	Wet preparation at the point of use .....	12
4.4.3	Storage systems .....	12
<b>5</b>	<b>Machine cleaning and disinfection</b> .....	<b>13</b>
5.1	Thermal method .....	14
5.1.1	Machine - alkaline .....	14
5.1.2	Machine - ph-neutral / enzymatic .....	15
5.2	Determination of the A0 value .....	15
5.3	Preparatory measures for machine reprocessing .....	16
5.3.1	Manual pre-cleaning .....	16
5.3.1.1	Camera cable / camera plug .....	16
5.3.1.2	Instrument connectors .....	16
5.3.1.3	Instruments with hollow spaces / channels .....	17
5.3.1.4	Instruments with movable parts - articulated instruments .....	17
5.4	Auxiliary resources required .....	17
5.5	Disassembly before cleaning .....	18

# Contents

5.6	Correct loading of washer-disinfector .....	21
5.6.1	Telescopes .....	21
5.6.2	Camera heads .....	22
5.6.3	Instruments with hollow spaces / channels .....	23
5.6.4	Instruments with movable parts - articulated instruments .....	25
5.6.5	Instruments with stopcocks .....	26
5.6.6	Accessories .....	26
5.6.6.1	Mechanical .....	26
5.6.6.2	Optical .....	27
5.6.6.3	Electrical .....	27
5.7	After machine reprocessing .....	27
5.8	Storage systems .....	27
5.8.1	RIWO SYSTEM TRAY .....	27
5.8.2	Reprocessing baskets .....	27
<b>6</b>	<b>Manual cleaning and disinfection .....</b>	<b>28</b>
6.1	Auxiliary resources required .....	28
6.2	Cleaning .....	29
6.2.1	Telescopes .....	30
6.2.1.1	Telescopes without working channel .....	30
6.2.1.2	Telescopes with working channel .....	31
6.2.2	Working instruments .....	32
6.2.2.1	Articulated instruments with irrigation connector .....	32
6.2.2.2	Suction and irrigation instruments .....	32
6.2.2.3	Resectoscopes .....	32
6.2.2.4	HF instruments / electrodes .....	33
6.2.3	Access instruments .....	33
6.2.3.1	Instruments with hollow spaces / channels .....	34
6.2.4	Accessories .....	34
6.2.4.1	Mechanical .....	34
6.2.4.2	Optical .....	35
6.2.4.3	Electrical .....	36
6.3	Ultrasonic cleaning .....	37
6.3.1	Cleaning in the ultrasonic bath .....	37
6.3.2	After ultrasonic cleaning .....	37
6.4	Disinfection .....	38
6.4.1	RIWO BOX SYSTEM .....	38
6.4.2	After disinfection .....	38
6.4.3	Accessories .....	38
6.4.3.1	Mechanical .....	38
6.4.3.2	Optical .....	39
6.4.3.3	Electrical .....	39
6.4.4	Reprocessing material .....	39
<b>7</b>	<b>Checks and maintenance .....</b>	<b>40</b>
7.1	Visual check .....	40
7.1.1	Telescopes / optical accessories .....	40
7.1.2	Working instruments .....	41
7.1.3	Access instruments .....	42
7.1.4	Accessories .....	43
7.1.4.1	Mechanical .....	43
7.1.4.2	Optical .....	43
7.1.4.3	Electrical .....	44

# Contents

7.2	Function check .....	44
7.3	Notes and instructions on maintenance before sterilization .....	45
7.3.1	Working instruments .....	45
7.3.2	Access instruments .....	46
<b>8</b>	<b>Sterilization .....</b>	<b>47</b>
8.1	Auxiliary resources required .....	47
8.2	Steam sterilization .....	48
8.2.1	Overview of steam sterilization procedures .....	48
8.2.1.1	Fractional pre-vacuum procedure .....	48
8.2.1.2	Other steam sterilization procedures .....	49
8.2.2	Accessories - information on special products .....	50
8.2.2.1	Optical .....	50
8.2.3	Assembly after sterilization .....	50
8.3	Low-temperature sterilization .....	51
8.3.1	Hydrogen peroxide plasma .....	51
8.3.1.1	STERRAD® 50 / 100S / 200 / NX™ and 100 NX™ .....	51
8.3.1.2	Sterilizers with Booster / diffusion amplifier in STERRAD® 50 / 100S / 200 .....	52
8.3.2	Gas .....	53
8.3.2.1	Ethylene oxide gas (EO) .....	53
8.3.2.2	Low temperature steam and formaldehyde (LTSF) .....	53
8.3.2.3	Hydrogen peroxide (V-PRO™ 1) .....	53
8.3.3	Peracetic acid / High Level Disinfection .....	54
8.3.3.1	STERIS SYSTEM 1® / STERIS SYSTEM 1E™ .....	54
8.4	Storage systems for sterilization .....	54
8.4.1	RIWO SYSTEM TRAY .....	54
8.4.2	Reprocessing baskets .....	54
8.4.3	Sterilization sieve basket system .....	55
8.5	Sterilization of cleaning accessories .....	55
<b>9</b>	<b>Storage .....</b>	<b>56</b>
9.1	After disinfection .....	56
9.2	After sterilization .....	56
<b>10</b>	<b>Repairs, returned products .....</b>	<b>56</b>
<b>11</b>	<b>Accessories for reprocessing .....</b>	<b>57</b>
<b>12</b>	<b>Product information on cleaning and care products .....</b>	<b>63</b>
12.1	Instrument oil 200.532 .....	63
12.1.1	Product description .....	63
12.1.2	Field of use .....	63
12.1.3	Additional notes and instructions for use .....	63
12.1.4	Product specifications .....	63
12.2	Instrument Grease 20012 .....	65
12.2.1	Product description .....	65
12.2.2	Field of use .....	65
12.2.3	Additional notes and instructions for use .....	65
<b>13</b>	<b>Literature .....</b>	<b>66</b>
<b>14</b>	<b>Index .....</b>	<b>70</b>



## General Information

### 1 General Information

#### 1.1 Manuals / Instructions for use

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

- ◇ **GA-J020**  
Manual on "Reprocessing of RICHARD WOLF Heat-Stable Instruments"
- ◇ **GA-J050**  
Manual on "Reprocessing of RICHARD WOLF Heat-Sensitive Instruments"
- ◇ **Product-specific Instructions for Use**  
They describe the specific use of the product with all the specifications required.
- ◇ **Latest version of the Manual / Instructions for Use**  
Ongoing new and further development of RICHARD WOLF products as well as technological progress require updating of the instruction manual 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-J020 / en / 2014-05 V17.0 / ...**

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 (Arbeitskreis Instrumentenaufbereitung).*

**Instrument reprocessing**  
**Reprocessing instruments maintaining their value**

*The brochure is available from RICHARD WOLF or can be downloaded free of charge from the webpage [www.a-k-i.org](http://www.a-k-i.org).*

#### 1.2 Material compatibility / proof of efficacy

RICHARD WOLF has tested the low temperature sterilization procedures described in section 1.10 "**Overview of reprocessing / material compatibility**" regarding 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.

## General Information

### 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](http://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 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. For the permissible procedures please refer to the following sections and/or the product-specific manuals.*



## General Information

### 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.*

## General Information

### 1.8 Characteristic features of steam sterilizability

The product number of RICHARD WOLF products indicates steam-sterilizability.

#### 1.8.1 Telescopes and instruments

##### ◇ Steam sterilizable

◆ Identification feature: the product numbers begin with "8".

Example: **8**654.433

##### ◇ Not steam sterilizable

◆ Identification feature: the product numbers begin with "4".

Example: **4**654.433

#### 1.8.2 Objective lenses and camera heads

##### ◇ Steam sterilizable

◆ Identification feature: the product numbers begin with "8".

Example: **8**5261.212

##### ◇ Not steam sterilizable

◆ Identification feature: the product numbers begin with "5".

Example: **5**268.221



#### **IMPORTANT!**

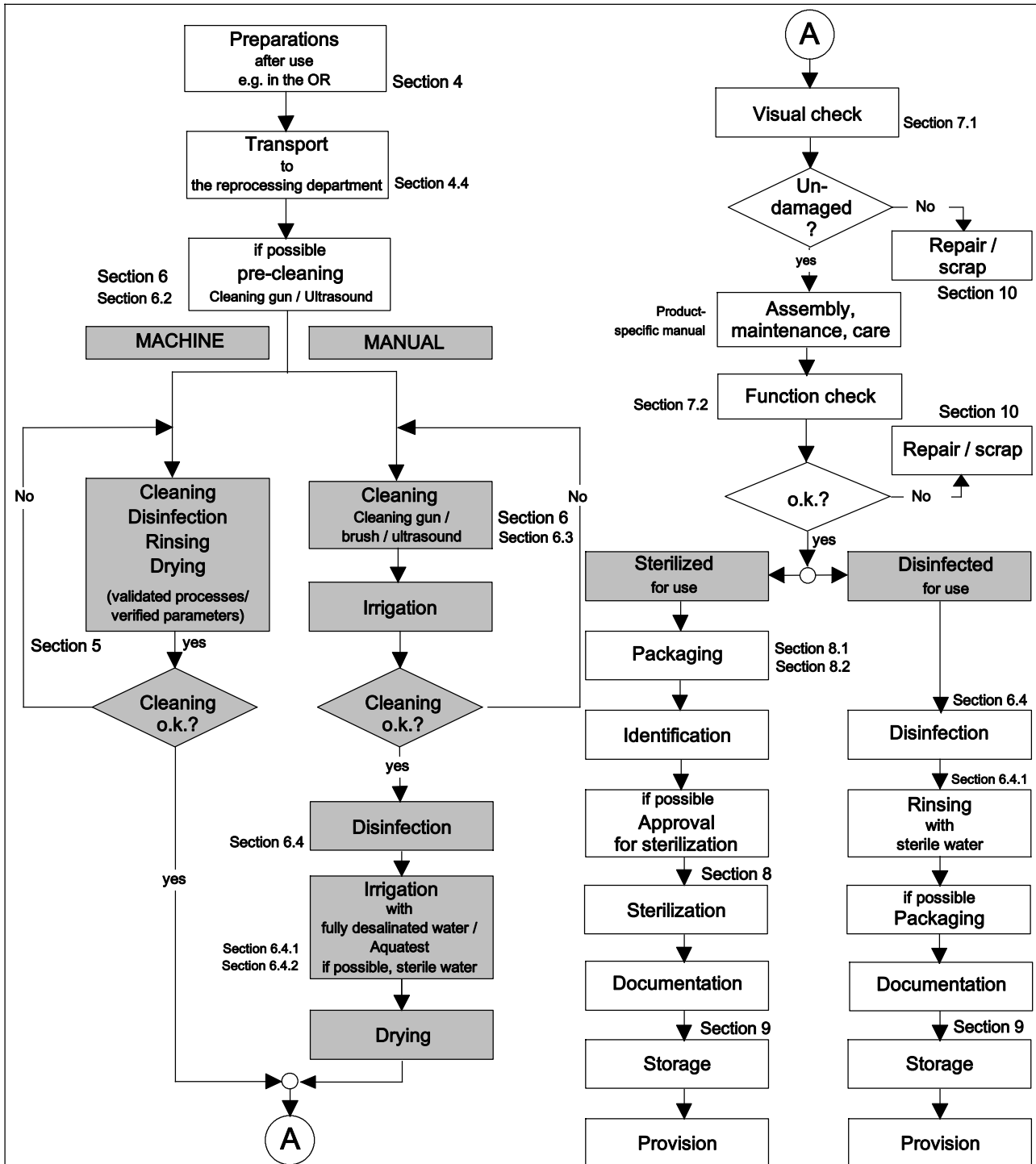
*For the reprocessing and/or sterilizability of products with product numbers **not** starting with "8", please refer to the product-specific manuals. Follow these manuals.*

# General Information

## 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-stable instruments. The sections mentioned refer to the corresponding methods and procedures.



# General Information

## 1.10 Overview of reprocessing / material compatibility

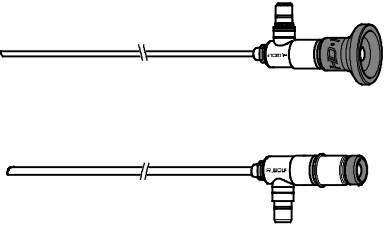
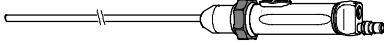
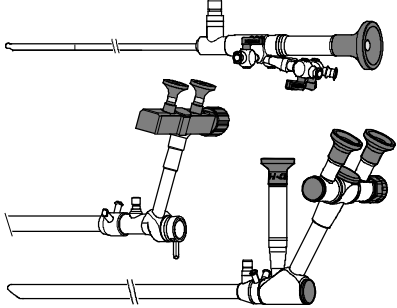
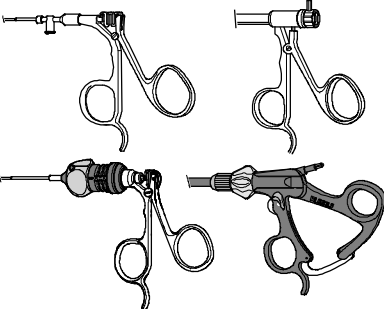
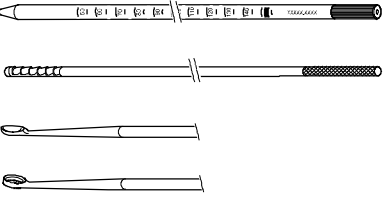
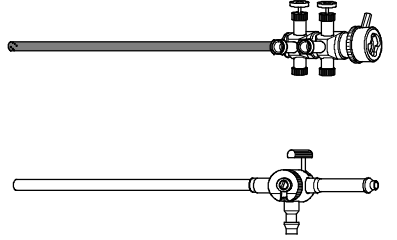
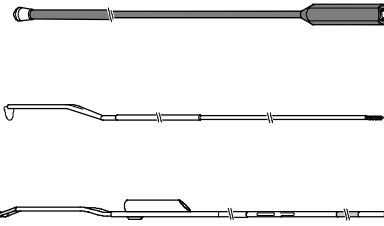
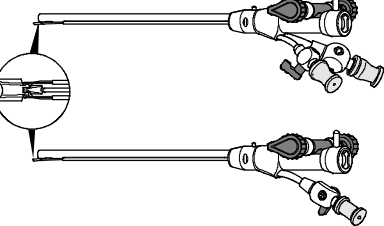
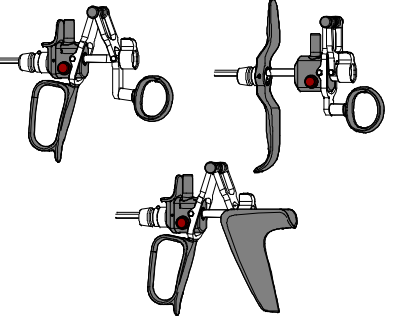
PRODUCTS			Telescopes		Working instruments				Access instruments
			8 x	4 x	Rigid	Flexible	Disposable, Sterile	Disposable, Unsterile <sup>05)</sup>	
PROCEDURES			8 x	4 x	Rigid	Flexible	Disposable, Sterile	Disposable, Unsterile <sup>05)</sup>	Access instruments
Preparation at the point of use	Condition	Wet preparation at the point of use	●	●	●	●	▲	▲	●
		Dry preparation at the point of use	●	●	●	●	▲	▲	●
Decontamination	Preparation	Pre-clean manually if necessary	●	●	●	●	○	●	●
	Cleaning	Manual	●	●	●	●	○	●	●
		Machine	Machine	●	60°	●	●	○	■
	Ultrasound		○	○	●	●	○	○	●
	Alkaline		●	●	●	●	○	■	●
	Containing citric acid		●	●	●	●	○	■	●
	Neutral / enzymatic	●	●	●	●	○	● <sup>03)</sup>	●	
	Containing peracetic acid	●	●	●	●	○	○	●	
	Rinsing <sup>01)</sup>		●	●	●	●	○	●	●
	Disinfecting <sup>02)</sup>	Chemical max. 60°C	●	●	●	●	○	●	●
Thermal max. 93°C		●	○	●	●	○	○	●	
Drying	T <sub>max</sub> in °C	100°	60°	100°	100°	○	■	100°	
Maintenance, checks		After decontamination	■	■	■	■	○	■	■
Sterilization	<b>Steam sterilization<sup>03)</sup></b>								
	Steam	Fractional pre-vacuum method 134°C / 273°F 132°C / 270°F	●	○	●	●	○	■	●
	<b>Low-temperature sterilization</b>								
	Hydrogen peroxide plasma	STERRAD <sup>®</sup> 50, 100S, 200	●	●	●	●	○	■	●
		STERRAD <sup>®</sup> NX <sup>™</sup> , 100NX <sup>™</sup>	●	●	●	●	○	■	●
	Gas	Ethylene oxide (EO)	●	●	●	●	○	■	●
		Low temperature steam and formaldehyde (LTSF)	●	●	●	●	○	■	●
		Hydrogen peroxide (STERIS V-PRO 1, V-PRO 1 Plus, V-PRO maX)	●	●	●	●	○	■	●
	Peracetic acid <sup>04)</sup> (Just in time)	STERIS SYSTEM 1 <sup>®</sup> STERIS SYSTEM 1E <sup>™</sup>	●	●	●	●	○	○	●
	x) Starting with product number "8..." / "4..." 01) Fully demineralized water recommended for the last rinsing cycle 02) Chemicals for reprocessing (see section 1.3) 03) Preferred procedure to be used 04) Products are not packed sterile (see section 8.3.3) 05) Before use			Legend: ● Permissible					
○ Not permissible / not necessary									
▲ Discard disposable item									
■ See product-specific instructions for use									

# General Information

PROCEDURES			Accessories											
			Mechanical				Optical							Electrical
			Rubber bulb 103.00 Double bulb 127.00	Reprocessible	Disposable, Sterile	Disposable, Unsterile 05)	Fiber light cables	Fluid light cables	Camera cables	8x)		5x)		
										Lenses	Camera heads	Adapters		
Preparation at the point of use	Condition	Wet preparation at the point of use	○	●	▲	▲	●	●	●	●	●	●	●	
		Dry preparation at the point of use	●	●	▲	▲	●	●	●	●	●	●	●	
Decontamination	Preparation	Pre-clean manually if necessary	○	●	○	●	●	●	●	●	●	●	●	
	Cleaning	Manual	●	●	○	●	●	●	●	●	●	●	●	
		Machine	Machine	●	●	○	■	●	○	●	●	●	●	●
			Ultrasound	○	○	○	○	○	○	○	○	○	○	○
			Alkaline	○	●	○	■	●	○	●	●	●	●	●
		Containing citric acid	○	●	○	■	●	○	●	●	●	●	●	
		Neutral / enzymatic	●	●	○	●03)	●	●	●	●	●	●	●	
		Containing peracetic acid	○	●	○	○	●	○	●	●	●	●	●	
	Rinsing 01)		●	●	○	●	●	●	●	●	●	●	●	
	Disinfecting 02)	Chemical max. 60°C	●	●	○	●	●	○	●	●	●	●	●	
Thermal max. 93°C		●	●	○	○	●	○	●	●	○	●	●		
Drying	T <sub>max</sub> in °C	100°	100°	○	100°	100°	○	100°	100°	60°	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 peroxide plasma	STERRAD® 50, 100S, 200	○	●	○	■	●	●	●	●	■	●	●	
		STERRAD® NX™, 100NX™	○	●	○	■	●	●	●	●	■	●	●	
	Gas	Ethylene oxide (EO)	○	●	○	■	●	○	●	●	●	●	●	
		Low temperature steam and formaldehyde (LTSF)	○	●	○	■	●	○	●	●	●	●	●	
		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 number "8..." / "5..." 01) Fully demineralized water recommended for the last rinsing cycle 02) Chemicals for reprocessing (see section 1.3) 03) Preferred procedure to be used 04) Products are not packed sterile (see section 8.3.3) 05) Before use			<b>Legend:</b> ● Permissible ○ Not permissible / not permissible ▲ Discard disposable item ■ See product-specific instructions for use										

**2 Illustration**

The following illustrations contain a selection of the wide range of RICHARD WOLF heat-stable instruments.  
Important notes on the reprocessing of these heat-stable instruments are described in the following sections and serve as an example.

TELESCOPES		
Rigid telescopes	CCD telescopes	Operating or compact telescopes
		
WORKING INSTRUMENTS		
Forceps, scissors, punches	Blunt, cutting	Suction, irrigation
		
Electrodes	Working inserts	Working elements
		
Fig. 1		

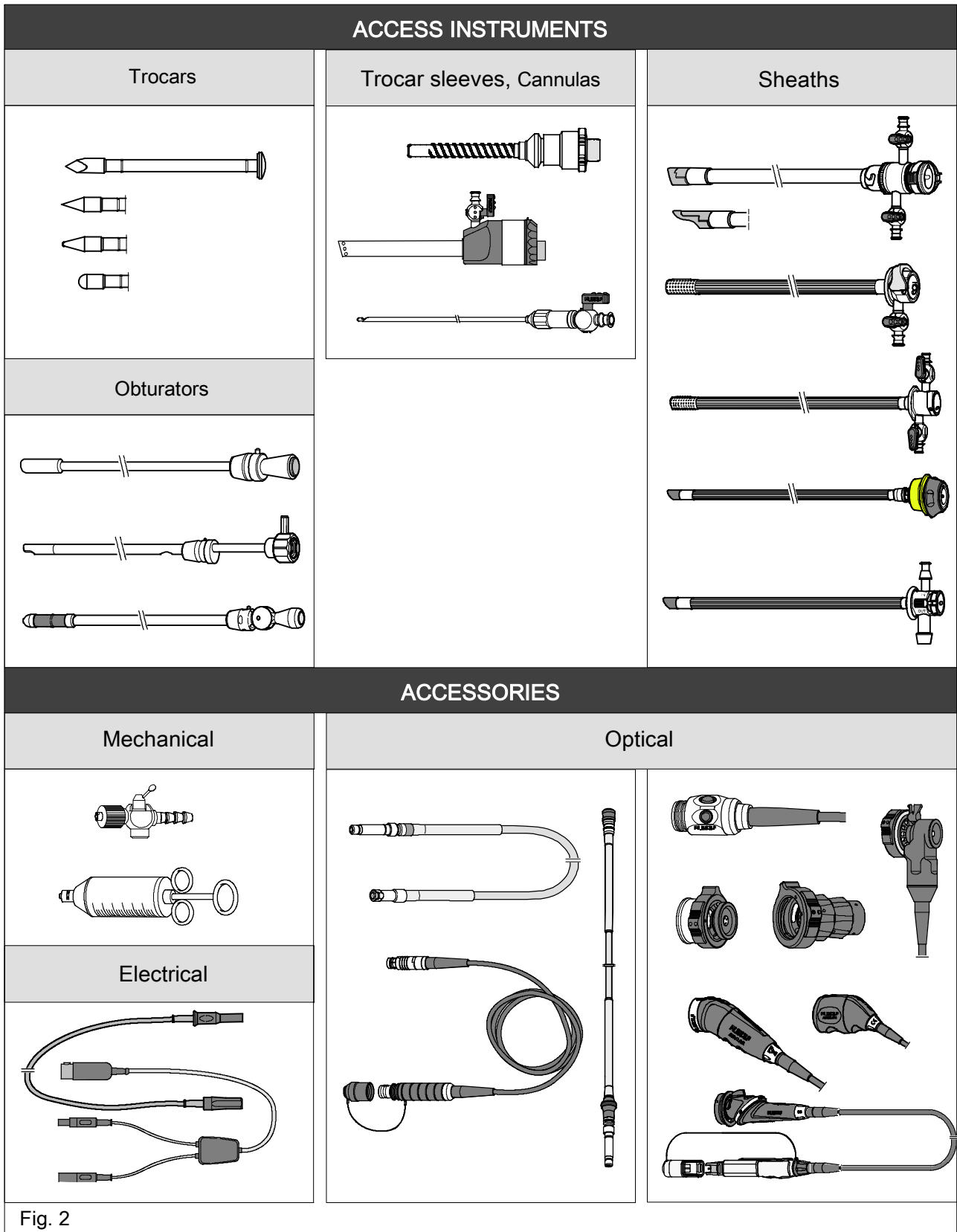


Fig. 2



## 3 Water quality

The water quality used for product reprocessing has a great influence on the preservation of 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](http://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<sup>\*)</sup> / ml during an incubation period of 44 ± 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\\_bzw.\\_anlage\\_5\\_377](http://www.gesetze-im-internet.de/trinkwv_2001/anlage_3_35_bzw._anlage_5_377)

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

## Preparation of instruments

### 4 Preparation of the instruments at the point of use



**CAUTION!**

**Danger of microbial carry-over!**

*To prevent a contamination of the camera plug when disconnecting the latter from the camera controller during the course of the operation, screw on / plug on the protection cap immediately after disconnection.*

A contaminated camera plug must be reprocessed manually before installing the protection cap.

- ◇ Immerse the camera plug 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).



**NOTE!**

*Drying of contaminant residues (blood, tissue particles, drugs, etc.) makes reprocessing difficult and increases the danger of corrosion.*

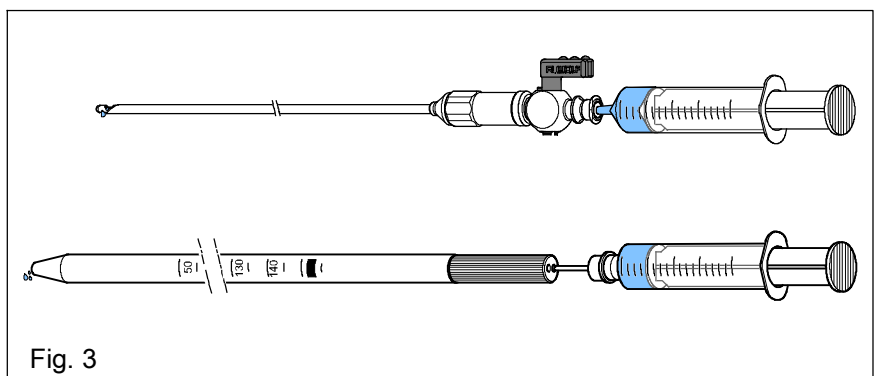
*The measures listed in the following must be carried out during use at the instrument table or immediately after:*

- ◇ Wipe the outside of the instruments with a lint-free disposable cloth to remove any coarse contamination / soiling.
  - ▶ Under no circumstances should the instruments be immersed in saline (NaCl solution)(pitting corrosion).
- ◇ Disassemble the instrument if necessary.
  - ▶ See product specific-instructions for use.
  - ▶ See section 5.5 "**Disassembly before cleaning**".
- ◇ Discard disposable items immediately, e.g.
  - ▶ Hygiene filter
  - ▶ Sealing membrane (membrane valve)
  - ▶ Disposable tube / tube set
- ◇ Lay down the instruments with due care to avoid damage.
- ◇ Open the stopcocks.

#### 4.1 Small-diameter instruments

**Fig. 3**

- ◇ Rinse out small-diameter instruments with sterile irrigation solution.
  - ▶ When rinsing out the channels make sure you do not splash irrigation solution into the environment.

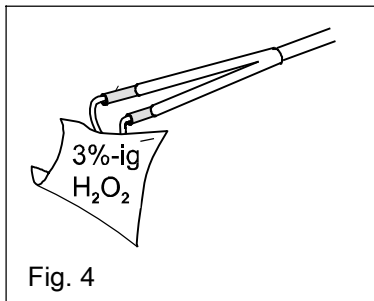


**Fig. 3**

## Preparation of instruments

### 4.2 HF instruments / electrodes

Encrusted coagulation surfaces impair the HF power.



**Fig. 4**

- ◇ Dissolve encrustations with 3% hydrogen peroxide solution ( $H_2O_2$  solution) and wipe off with a compress.
- ◇ If necessary, the coagulation surfaces can be wiped at intervals during the operation using a compress.
- ◇ Then rinse with sterile water.

### 4.3 Reprocessable tube and hose systems

Disassemble and rinse out reprocessable (reusable) hose / tube systems.

### 4.4 Transport

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

#### 4.4.1 Dry preparation at the point of use

In the case of machine reprocessing, dry preparation at the point of use is the method of choice, because residues from the solution for wet decontamination at the point of use can impair the cleaning result in the WD (**W**asher **D**isinfector).

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

#### 4.4.2 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 residues from 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.

#### 4.4.3 Storage systems

For a safe and trouble-free transport to the reprocessing room, we recommend using the specialized transport and storage systems.

For further information please see:

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

## 5 Machine cleaning and disinfection

### **IMPORTANT!**

*We recommend that you avoid using Cleaning and disinfectant solutions in powder form, because undissolved particles can clog narrow channels and discolor the instruments.*

*When using powder-based solutions, make sure that all the powder has dissolved. Use only disinfectants whose efficacy and compatibility with rigid telescopes and endoscopic accessories has been verified and approved.*

#### ◆ See section 1.3 **"Chemicals for reprocessing"**

*For the concentration and exposure time of the cleaning and disinfectant agent used, please refer to the specifications issued by the manufacturer of the chemicals.*

*Do not use any care products for the last rinsing, as these can cause deposits on the products and damage to the plastic materials.*

### **IMPORTANT!**

*Use only WD devices (**W**asher **D**isinfectant **D**evice), that*

◆ *are designed by the manufacturer for rigid telescopes and endoscopic accessories.*

◆ *are equipped with a special load carrier, allowing the connection of rigid instruments and endoscopic accessories to the WD device and the rinsing of channels.*

*The certified cleaning agents and disinfectants must be compatible with each other, with the procedure as well as with the rigid telescope and 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.*

### **IMPORTANT!**

*In the case of instruments which due to hard-to-remove contaminants need to be cleaned manually or pre-cleaned in an ultrasonic bath, follow the corresponding sections of this manual.*

◆ *Section 5.3.1 **"Manual pre-cleaning"**.*

◆ *Section 6.3 **"Ultrasound cleaning"**.*

### **NOTE!**

*All steam sterilizable heat-stable instruments can be machine reprocessed unless their specific instruction manual requires otherwise.*

*For the machine reprocessing of small parts, use a small parts sieve or utensils basket, respectively, made by the washer-disinfector manufacturer.*

## 5.1 Thermal method

For the machine reprocessing of heat-stable instruments we recommend a **thermal method** using

- ◆ an alkaline cleaner and neutralizer or
- ◆ a neutral or enzymatic cleaner, respectively.
- ◆ a procedure which has been optimized for telescopes avoiding temperature-leaps.

**Thermal procedures** disinfect purely thermally, without the addition of disinfectant.

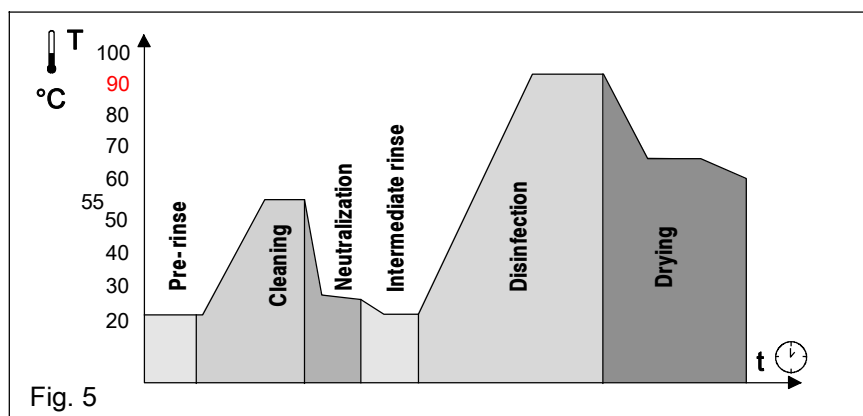
For the above, note and observe the following:

- ◆ Follow the country specific guidelines as well as
- ◆ The standard DIN EN ISO 15883.

The following processes have been proven successful and have been validated by RICHARD WOLF:

### 5.1.1 Machine - alkaline

Fig. 5



#### Program (without disinfection step) - alkaline

- ◇ >4 min of precleaning with cold water
- ◇ empty
- ◇ >6 min of cleaning with a cleaning agent at approx. 55°C
- ◇ empty
- ◇ >3 min of neutralization\*) (<40°C)
- ◇ empty
- ◇ >2 min of intermediate rinsing (<40°C)
- ◇ empty

\*) Depending on the water quality, add a neutralization solution based on citric acid.

#### Disinfection

- ◇ Carry out thermal machine disinfection following the national requirements with regard to the A0 value (see DIN EN ISO 15883).

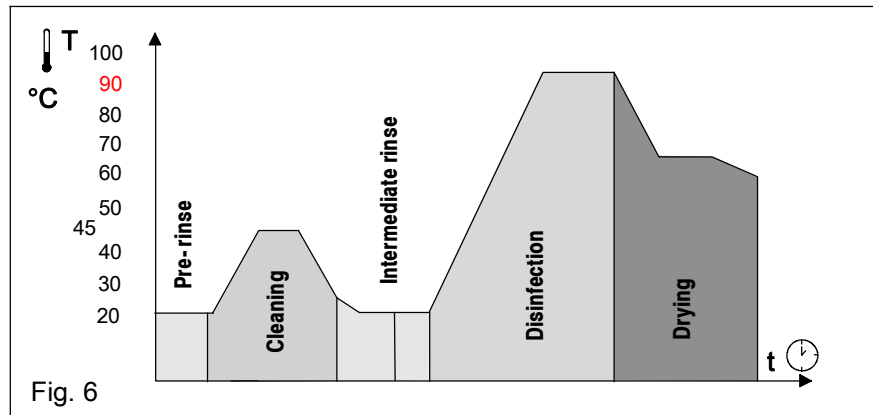


#### **IMPORTANT!**

*Do not use any drying aids (such as rinse aids) for the last rinsing cycle (disinfection). These may remain on the surface causing damage to the instrument due to unfavorable interference.*

## 5.1.2 Machine - ph-neutral / enzymatic

Fig. 6



### Program (without disinfection step) - ph-neutral / enzymatic

- ◇ >4 min of precleaning with cold water
- ◇ empty
- ◇ >6 min of cleaning with a cleaning agent at approx. 45°C
- ◇ empty
- ◇ >2 min of intermediate rinsing (<40°C)
- ◇ empty
- ◇ >2 min of intermediate rinsing (<40°C)
- ◇ empty

### Disinfection

- ◇ Carry out thermal machine disinfection following the national requirements with regard to the A<sub>0</sub> value (see DIN EN ISO 15883).

### **IMPORTANT!**

*Do not use any drying aids (such as rinse aids) for the last rinsing cycle (disinfection). These may remain on the surface causing damage to the instrument due to unfavorable interference.*

## 5.2 Determination of the A<sub>0</sub> value

The **A<sub>0</sub> value** of a disinfection procedure using moist heat represents the killing of microorganisms (disinfection effect) on a contaminated product, achieved at a specific temperature over a specific time.

As the number and kind of microorganisms on the product subjected to reprocessing is unknown (heat resistant viruses, e.g. Hepatitis B virus) and varies greatly, we recommend an **A<sub>0</sub> value** of **3000** for machine decontamination.

How to calculate an **A<sub>0</sub> value** together with the **D values** and **z values** required are described e.g. in the standard DIN EN ISO 15883.

## Machine reprocessing

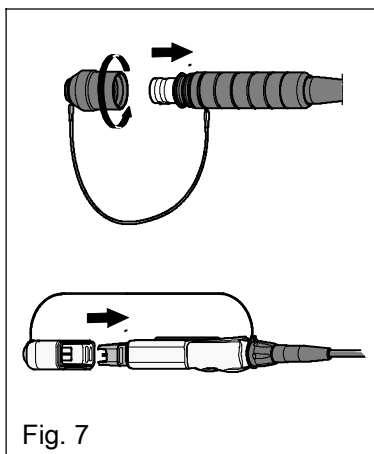
### 5.3 Preparatory measures for machine reprocessing

#### 5.3.1 Manual pre-cleaning

##### 5.3.1.1 Camera cable / camera plug

A contaminated camera plug must be reprocessed manually before installing the protection cap.

- ◇ Immerse the camera plug 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).



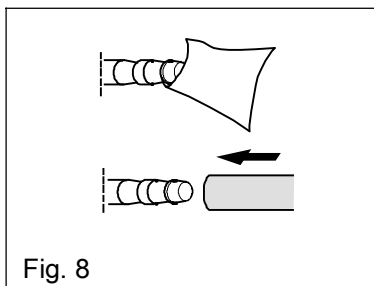
**Fig. 7**

- ◇ Screw or plug the protection cap onto the camera plug.

 **IMPORTANT!**

*Reprocess the camera plug only with the protective cap 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).*

##### 5.3.1.2 Instrument connectors



**Fig. 8**

- ◇ Treat any instrument connectors which are covered by connection tubes with a certified cleaning disinfectant solution before placing them into the washer-disinfector.



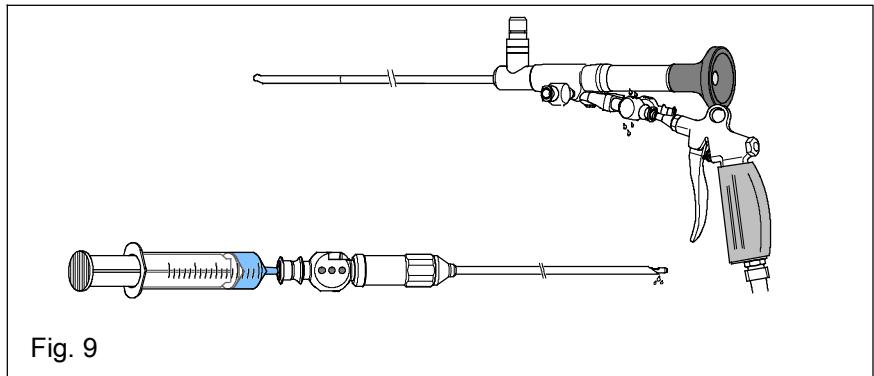
## Machine reprocessing

### 5.3.1.3 Instruments with hollow spaces / channels

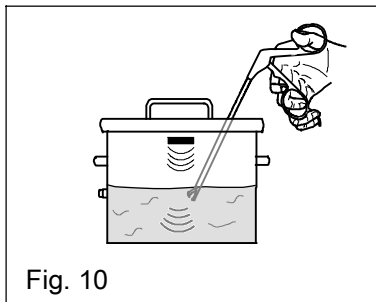
- ◇ Remove stopcocks i.e. stopcocks with removable plugs, see Fig. 18 / Fig. 19, open maintenance-free stopcocks.
- ◇ to remove any clogging and residues, rinse out hollow spaces (channels) using a cleaning gun or a syringe filled with water. We recommend applying
  - ◆ at least 5 subsequent pressure surges (2.5 - 4 bar) or
  - ◆ at least 20 s under permanent pressure.

#### Fig. 9

- ◇ Examples:
  - ◆ Instruments with small (narrow) channels
  - ◆ Cannulas



### 5.3.1.4 Instruments with movable parts - articulated instruments



#### Fig. 10

- ◇ Example:
  - ◆ Forceps, scissors, punches
- ◇ Pre-clean articulated instruments in an ultrasonic bath if necessary.
  - ◆ See section 6.3 "Ultrasonic cleaning"

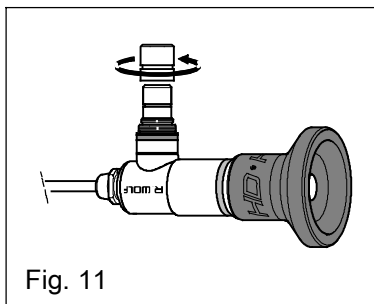
## 5.4 Auxiliary resources required

- ◇ Washer-disinfector
  - ◆ Follow the WD manufacturer's notes / instruction manual.
  - ◆ Follow the notes in section 1.10 "Overview of reprocessing / material compatibility".
- ◇ Loading basket for MIS
  - ◆ Utensils basket
- ◇ Telescope reprocessing baskets
- ◇ Lint-free disposable cloth and swab
- ◇ Cleaning brushes
- ◇ Cleaning gun (rinsing pressure 2.5 - 4 bar)
- ◇ Fully demineralized water
  - ◆ See section 3 "Water quality"
- ◇ Rinsing adapter, if necessary

## Machine reprocessing

### 5.5 Disassembly before cleaning

- ◇ Disassemble the heat-stable instruments if necessary.
- See product specific-instructions for use.
- See the following illustrations as examples.

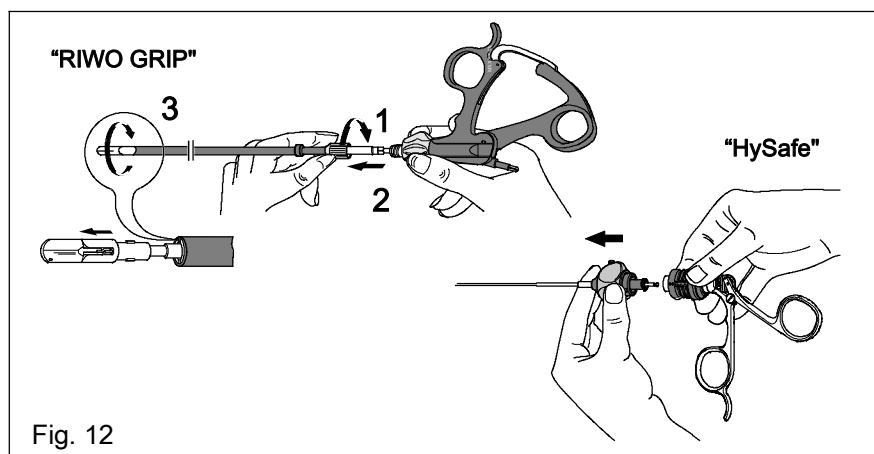


**Fig. 11**

- ◇ Example:
- Telescopes

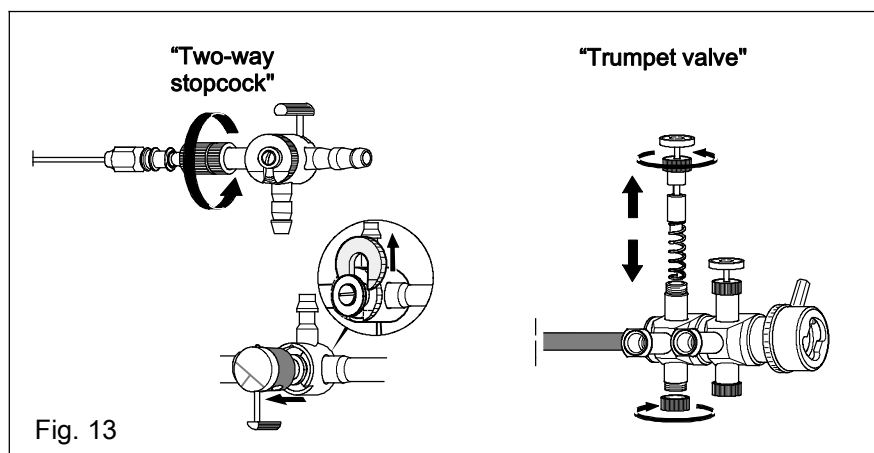
**Fig. 12**

- ◇ Example:
- Modular forceps and scissors system



**Fig. 13**

- ◇ Example:
- Suction and irrigation instruments



**Fig. 14 / Fig. 15**

- ◇ Example:
- ▶ "Shark" resectoscope sheaths

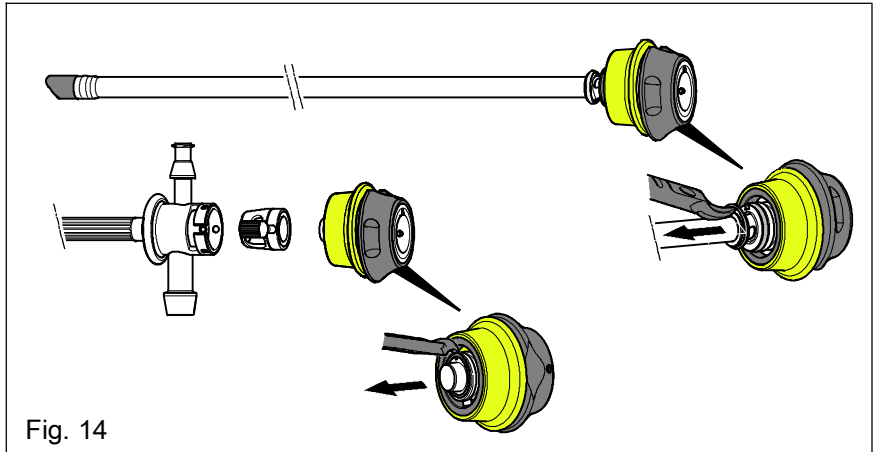


Fig. 14

- ▶ Resectoscope sheaths

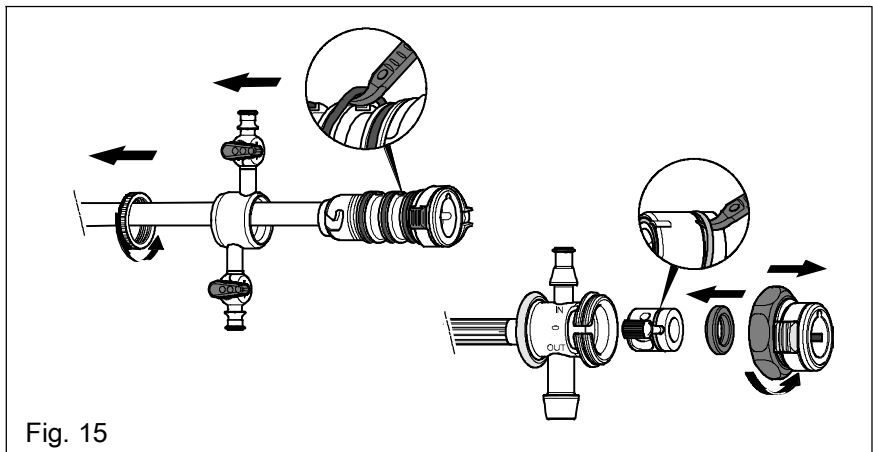


Fig. 15

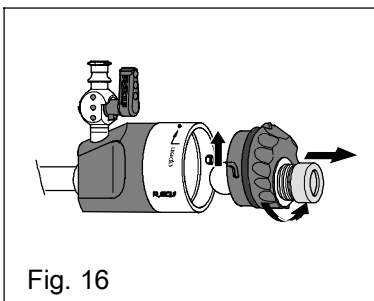
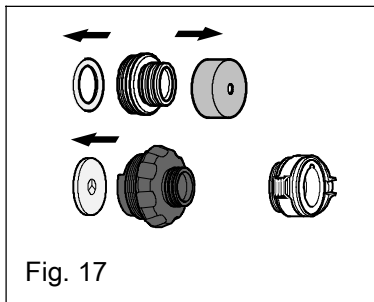


Fig. 16

**Fig. 16**

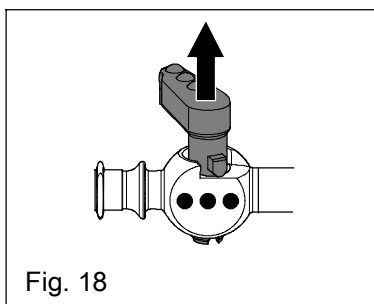
- ◇ Example:
- ▶ RIWO-ART "Automatic Resterilizable Trocar sleeve"

## Machine reprocessing



**Fig. 17**

- ◇ Examples:
  - ◆ Adapter
  - ◆ Sealing membrane (membrane valve)
  - ◆ Sealing caps

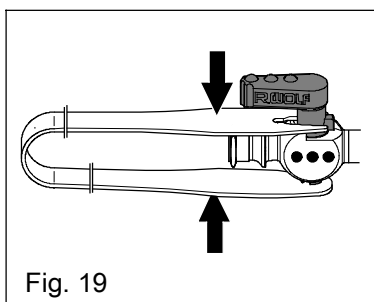


**Fig. 18**

- ◇ Example:
  - ◆ Stopcocks with removable plugs

**Without disassembly tool**

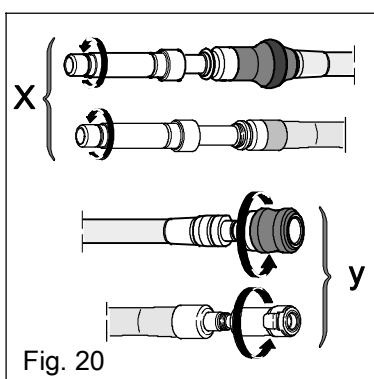
- ◇ Remove stopcock plug.
  - ◆ Stopcock plug disengages from stopcock housing.



**Fig. 19**

**With disassembly tool**

- ◇ Push forward the disassembly tool as shown in Fig. 19 and compress.
  - ◆ Stopcock plug disengages from stopcock housing.
- ◇ Remove stopcock plug.



**Fig. 20**

- ◇ Example:
  - ◆ Fiber light cable
- ◇ Remove the adapters between the projector and the light cable (x) and between the light cable and the endoscope (y).

## 5.6 Correct loading of washer-disinfector

To avoid damage in the WD as well as to the instruments, observe the following items:

- ◇ All instruments must be securely fastened to the carrier rack of the washer-disinfector.
- ◇ Place the instruments in such a way that
  - ◆ they do not touch each other (no spray shadows) or damage each other.
  - ◆ all internal and external surfaces can be reached by the rinsing medium.
- ◇ Do not overload the washer-disinfector.
- ◇ Connect the Luer connectors to the carrier rack of the washer-disinfector using a suitable hose system and check for secure connections.

### 5.6.1 Telescopes

**Fig. 21**

- ◇ Place telescopes in special reprocessing baskets.
  - ◆ See product specific-instructions for use.
  - ◆ See section 11 "Accessories for reprocessing".

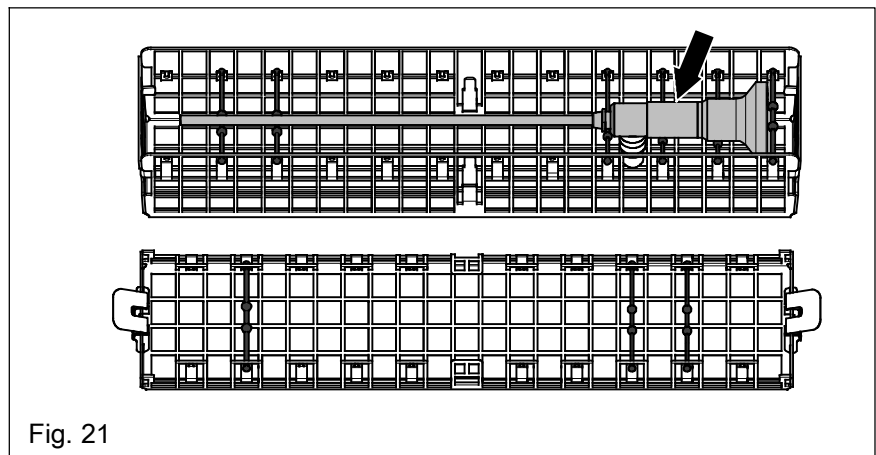


Fig. 21

**Fig. 22**

- ◇ Place telescopes with working channel in special reprocessing baskets and connect them to the loading basket using a suitable tube system.

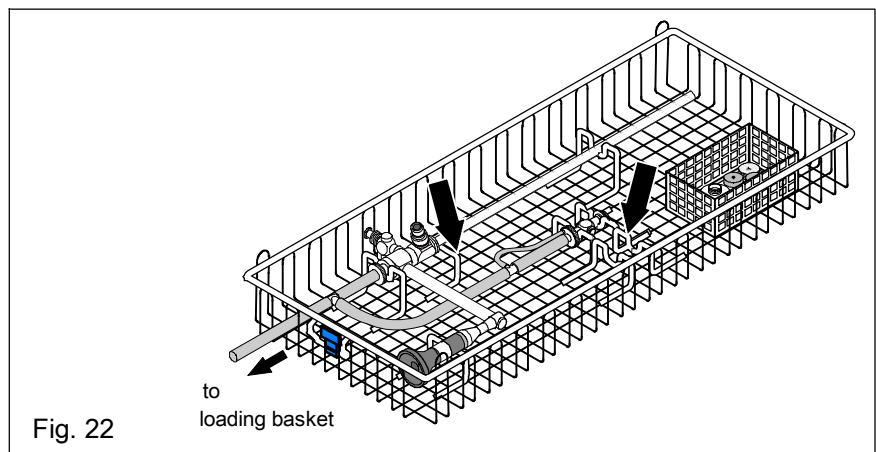


Fig. 22

# Machine reprocessing

## 5.6.2 Camera heads

- ◇ Not all camera heads can be machine reprocessed.
  - ◆ See product specific-instructions for use.
  - ◆ See section 1.10 "Overview of reprocessing / material compatibility".

**Fig. 23**

- ◇ Example:

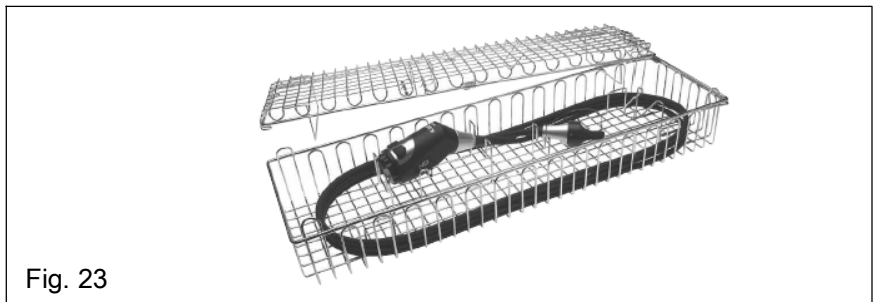


Fig. 23

## Machine reprocessing

### 5.6.3 Instruments with hollow spaces / channels

- ◇ Connect special reprocessing systems or inserts, respectively, tailored for the instrument set to the carrier rack via a suitable hose system and connect to the washer-disinfector in such a way that all channels and hollow spaces are duly rinsed out.

**IMPORTANT!**

*Close any rinsing holes that are not used with dummy plugs (x).*

*When selecting the spray nozzles, follow the instructions of the washer-disinfector manufacturer.*

*The length of the rinsing nozzles should at least be  $\frac{2}{3}$  of the total length of the instruments.*

**Fig. 24**

- ◇ Example:

**Modular bipolar instruments, ERAGON**

consisting of:

- ◆ Bipolar handle (A1)
- ◆ Sheath tube (A2)
- ◆ Inner part (A3)

**RIVO-ART Automatic Resterilizable Trocar sleeve**

consisting of:

- ◆ Sheath (B1)
- ◆ Housing cover, O-ring, sealing cap (B2)
- ◆ Stopcock plug (B3)

**Dilation guide sleeve (C)**

**Flexible trocar sleeve (D)**

**Veress cannula (E)**

**Suction and irrigation tube (F)**

**Bipolar button electrode (G)**

**Continuous irrigation inner sheath (H)**

**Dummy plug (X)**

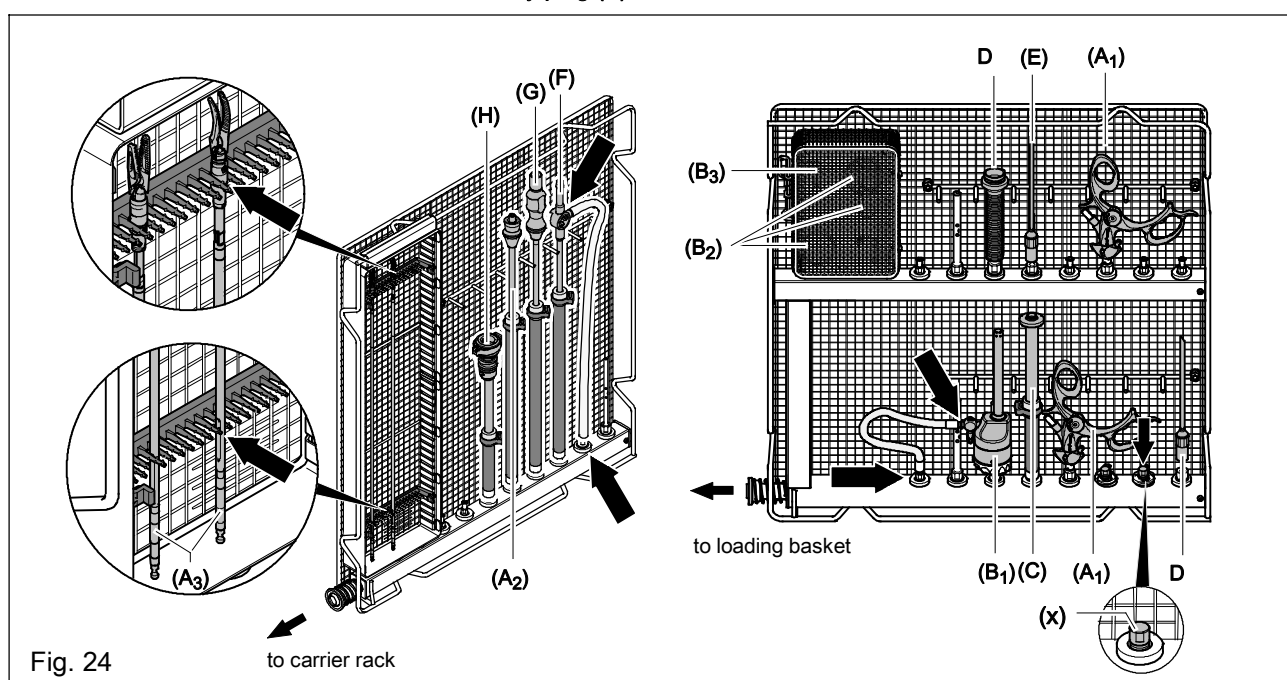


Fig. 24



**Fig. 25**

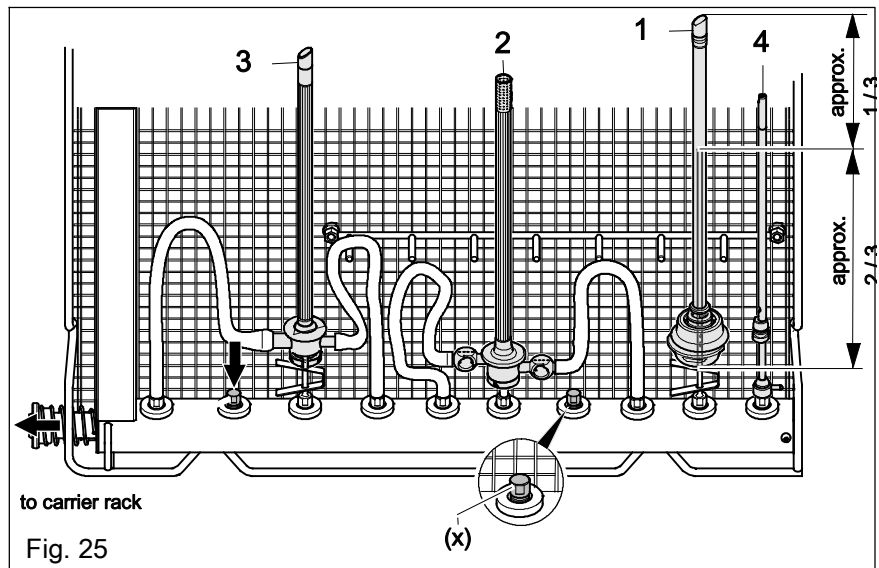
◇ Example:

**Resectoscope**

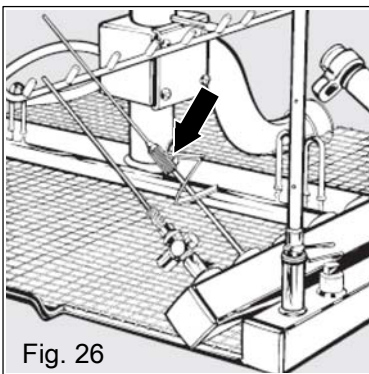
- ▶ Inner sheath (1)
- ▶ Outer sheath (2)
- ▶ Resectoscope sheath with central stopcock (3)

**Viewing obturator (4)**

**Dummy plug (X)**



**Fig. 25**

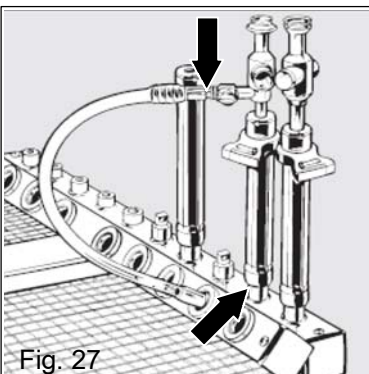


**Fig. 26**

**Fig. 26**

◇ Example:

- ▶ Cannulas



**Fig. 27**

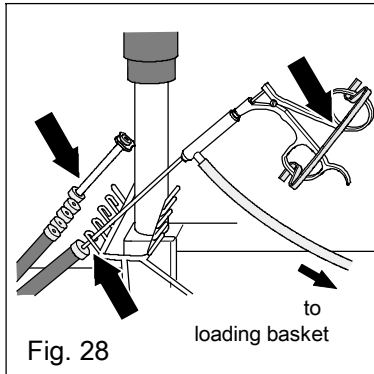
**Fig. 27**

◇ Example:

- ▶ Trocar and instrument sleeves

## Machine reprocessing

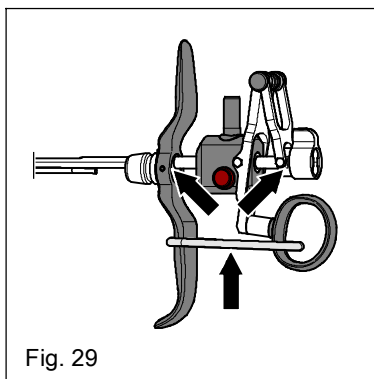
### 5.6.4 Instruments with movable parts - articulated instruments



The jaw sections must be open.

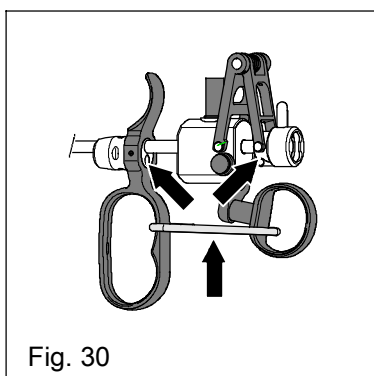
**Fig. 28**

- ◇ Example:
  - ◆ Forceps, scissors, punches with irrigation connector
- ◇ Connect articulated instruments with irrigation connector via a suitable hose system to the carrier rack of the washer-disinfector..
- ◇ To ensure complete cleaning in the joint, place articulated instruments in open condition into the washer-disinfector. For this purpose RICHARD WOLF offers cleaning clamps.
  - ◆ See section 11 **"Reprocessing of accessories"**.
- ◇ Place the cleaning clamp between the grips.
  - ◆ The articulated instruments are held open.



**Fig. 29/ Fig. 30**

- ◇ Example:
  - ◆ Working elements
- ◇ To allow thorough cleaning in the area of the electrode lock, avoid any contact between the electrode lock and adjacent surfaces.
  - ◆ For this purpose RICHARD WOLF offers a cleaning clip.
- ◇ Place the cleaning clamp between the grips.
  - ◆ The electrode lock is in the cleaning position.



**IMPORTANT!**

*If you do not use the cleaning clamp, the concealed supporting surfaces must be pre-cleaned manually.*

## Machine reprocessing

### 5.6.5 Instruments with stopcocks

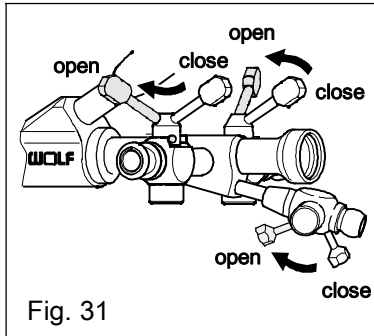


Fig. 31

#### Maintenance-free stopcocks

##### Fig. 31 / Fig. 32

- ◇ Example:
  - ◆ Ureterorenoscope
- ◇ Do not disassemble the stopcocks.
- ◇ Open the stopcocks.

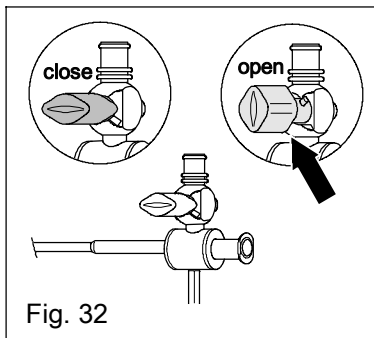


Fig. 32

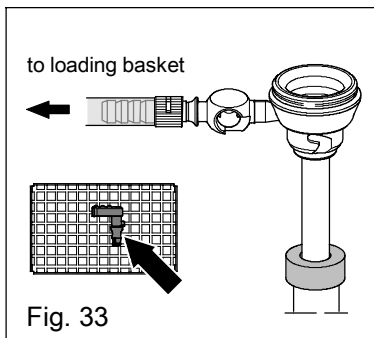


Fig. 33

#### Stopcocks with removable plugs

##### Fig. 33

- ◇ Example:
  - ◆ Resectoscope continuous irrigation inner sheath
- ◇ Place the stopcock plug into a small parts basket.

### 5.6.6 Accessories

#### 5.6.6.1 Mechanical

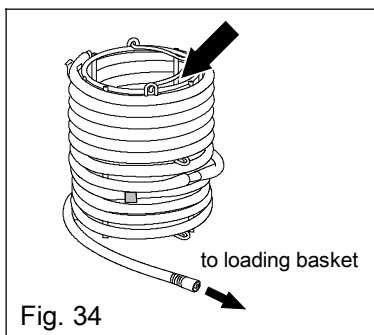


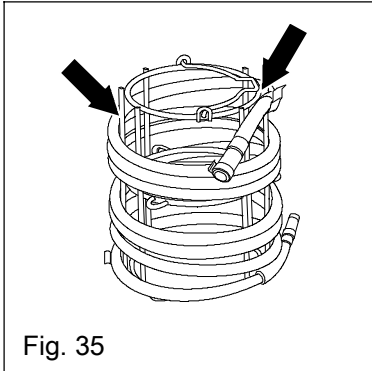
Fig. 34

##### Fig. 34

- ◇ Example:
  - ◆ Reprocessable tubes / hoses
- ◇ Wind up the hoses on special devices inside the washer-disinfector, fasten the loose end and connect.

## Machine reprocessing

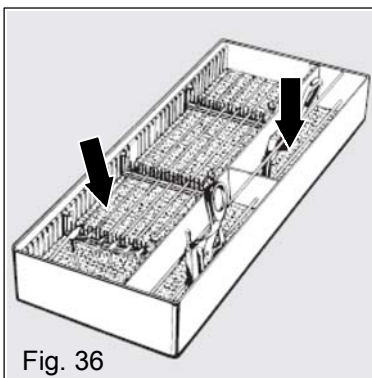
### 5.6.6.2 Optical



**Fig. 35**

- ◇ Example:
  - ◆ Fiber light cable
- ◇ Wind up the fiber light cable on special devices inside the washer-disinfector and fasten the loose end.

### 5.6.6.3 Electrical



**Fig. 36**

- ◇ Example:
  - ◆ HF monopolar / bipolar connection cable
- ◇ Place the HF monopolar / bipolar connection cable into a utensils basket.

- ◇ Example:
  - ◆ Lenses
- ◇ Not all objective lenses can be machine-reprocessed.
  - ◆ See product specific-instructions for use.
  - ◆ See section 1.10 "**Overview of reprocessing / material compatibility**".

## 5.7 After machine reprocessing

- ◇ Check all parts 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 "**Checks and maintenance**".
  - ◆ See product specific-instructions for use.

## 5.8 Storage systems

### 5.8.1 RIWO SYSTEM TRAY

- ◇ Remove silicone peg mats from the RIWO SYSTEM TRAYS and reprocess separate from the RIWO SYSTEM TRAYS.
- ◇ The peg mats can be reprocessed up to 93° C using the thermal method.

### 5.8.2 Reprocessing baskets

- ◇ The peg mats can be reprocessed up to 93° C using the thermal method.
  - ◆ See section 5.6.1 "**Telescopes**"
  - ◆ See section 5.6.2 "**Camera heads**" (if steam-sterilizable)

## 6 Manual cleaning and disinfection

### **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”**

*For the concentration and exposure time of the cleaning agent and disinfectant used please follow the chemical manufacturer's instructions.*

*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!**

*After cleaning / disinfection, check all parts for damage and replace if necessary.*

◆ See section 7 **“Checks and maintenance”**.

◆ See product specific-instructions for use.

### 6.1 Auxiliary resources required

- ◇ Sterile lint-free disposable cloth, swab and cotton swab
- ◇ Cleaning brushes
- ◇ Cleaning gun (rinsing pressure 2.5 - 4 bar) or conventional syringe
- ◇ Storage systems
  - ◆ We recommend using a RIWO BOX (see section 11)
- ◇ Certified cleaning solution / certified disinfectant solution
  - ◆ See section 1.3 **“Chemicals for reprocessing”**.
- ◇ Ultrasonic bath
  - ◆ Follow section 1.10 **“Overview of reprocessing / material compatibility”**.
  - ◆ Follow section 6.3 **“Ultrasonic cleaning”**.
- ◇ Tap water
- ◇ Fully demineralized water
  - ◆ See section 3 **“Water quality”**.
- ◇ Compressed air
  - ◆ After disinfection, use filtered compressed air

## Manual reprocessing

### 6.2 Cleaning

**IMPORTANT!**

*Clean the instruments manually with care and thoroughly. Residues such as detergents, blood, pus, protein residues etc. can impair an ensuing disinfection or sterilization.*

**IMPORTANT!**

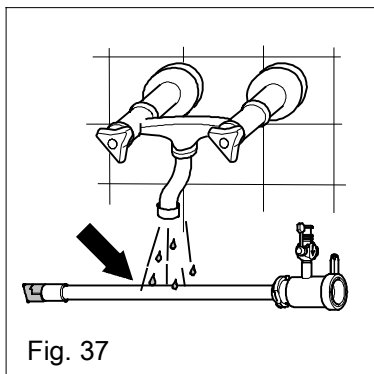
*Instruments with hollow spaces!*

*When immersing instruments with hollow spaces in a certified cleaning solution, make sure that*

- ◆ *The hollow spaces / cavities are patent (free).*
- ◆ *The air bubbles can escape from the hollow spaces / channels by moving or holding the instrument at an angle.*
- ◆ *All surfaces (inside / outside) are completely wetted with the certified cleaning solution.*

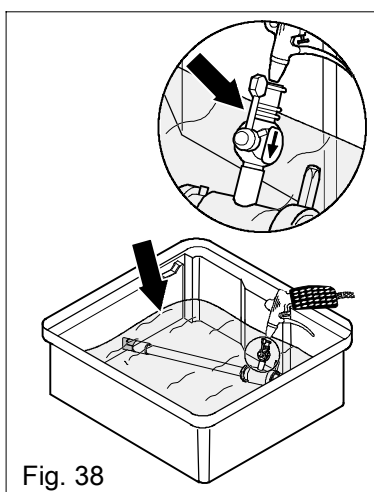
**NOTE!**

*For material saving and thorough cleaning of mechanically sensitive instruments an ultrasonic bath can be used in addition.*



**Fig. 37**

- ◇ Rinse the parts with water - **maximum 45°C**.
  - ◆ High temperatures can cause protein denaturation.
- ◇ Disassemble the instruments if necessary.
  - ◆ See product specific-instructions for use.
  - ◆ See section 5.5 "Disassembly before cleaning - examples".



**Fig. 38**

- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
  - ◆ See section 1.3 "Chemicals for reprocessing".



**CAUTION!**

**Spray contamination!**

*To avoid spray contamination with microorganisms in the environment, always rinse out and brush channels while the instrument is immersed in cleaning solution.*

*Follow the applicable staff protection guidelines.*

**Maintenance-free stopcocks**

- ◇ Open the stopcocks.
- ◇ Clean hollow spaces with suitable cleaning brushes.
- ◇ Rinse out narrow channels with a cleaning gun.

## Stopcocks with removable plugs

**Fig. 39**

- ◇ Clean the stopcock plug and the stopcock housing with a suitable cleaning brush.
- ◇ Rinse out the stopcock housing with a cleaning gun.
- ◇ Then thoroughly re-rinse with fully demineralized water.

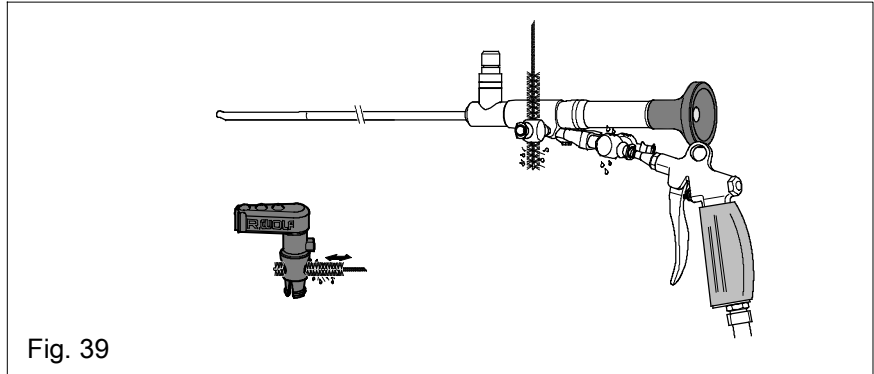


Fig. 39

## 6.2.1 Telescopes

Poorly cleaned telescopes will offer a blurred field of view and therefore limited vision. There is an essential light loss at the light entry and light exit surfaces.



### **CAUTION!**

*Do not clean telescopes in the ultrasonic bath!*



### **IMPORTANT!**

*Do not use any metal items (such as tweezers etc.) for cleaning, as these can damage the glass surfaces and the ground fiber ends.*

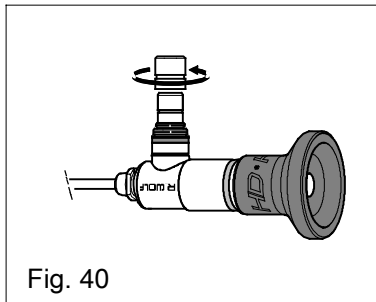


Fig. 40

**Fig. 40**

- ◇ Remove adapter for endoscope and place in a small parts sieve or utensils basket.

### 6.2.1.1 Telescopes without working channel

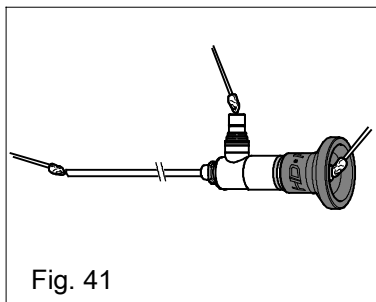


Fig. 41

**Fig. 41**

- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry the outside surfaces with a lint-free disposable cloth or swab.
- ◇ Remove any soiling on glass surfaces or on the light entry or light exit areas by gentle wiping with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).



## 6.2.1.2 Telescopes with working channel

**Fig. 42**

- ◇ Clean hollow spaces with suitable cleaning brushes.
- ◇ Rinse out narrow channels with a cleaning gun.
- ◇ Then thoroughly re-rinse with fully demineralized water.

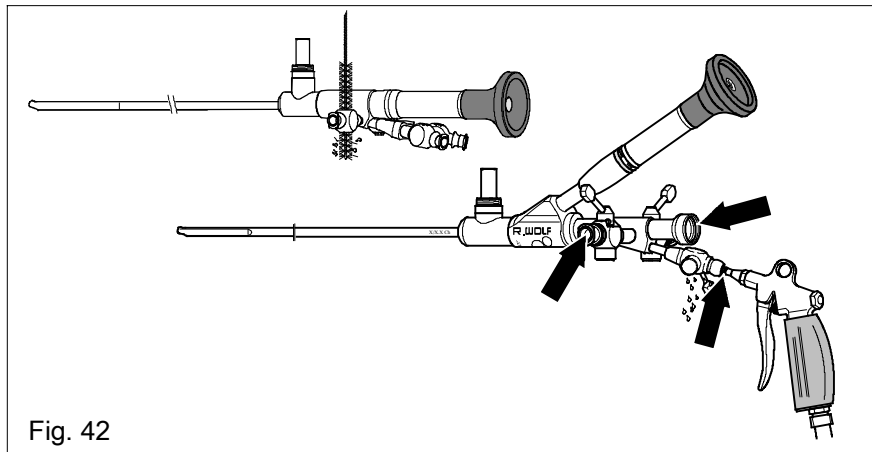


Fig. 42

**Fig. 43**

- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.
- ◇ Remove any soiling on glass surfaces or on the light entry or light exit areas by gentle wiping with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).

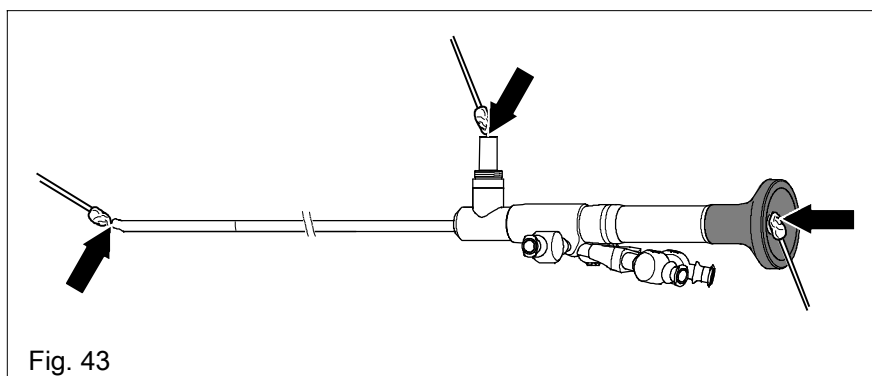
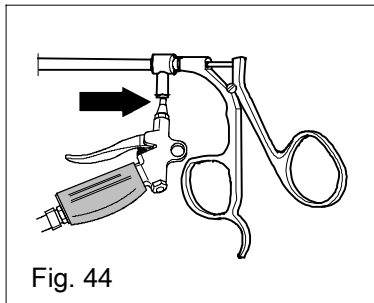


Fig. 43

## Manual reprocessing

### 6.2.2 Working instruments

#### 6.2.2.1 Articulated instruments with irrigation connector



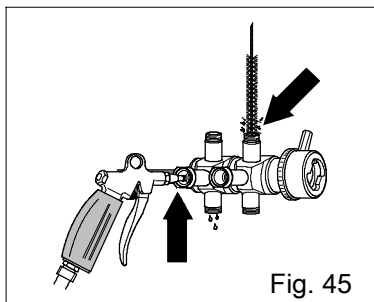
**Fig. 44**

- ◇ Example:
  - ◆ Forceps, scissors, punches
- ◇ Remove the luer sealing cap.
- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Rinse out the channel using a cleaning gun.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.

 **IMPORTANT!**

*Reinstall the luer locking cap only after sterilization.*

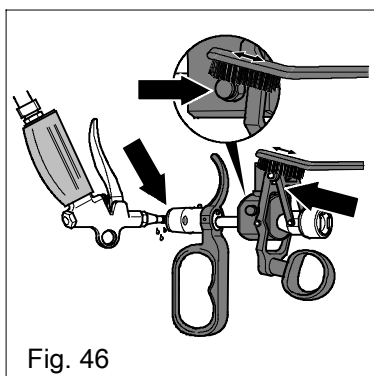
#### 6.2.2.2 Suction and irrigation instruments



**Fig. 45**

- ◇ Example:
  - ◆ Suction and irrigation tubes
- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Clean hollow spaces with suitable cleaning brushes.
- ◇ Rinse out narrow channels with a cleaning gun.
  - ◆ Remove any clogging of the suction tube with a cleaning mandril.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.

#### 6.2.2.3 Resectoscopes



**Fig. 46**

**Fig. 46/ Fig. 47**

- ◇ Example:
  - ◆ Working elements
- In the case of urine salt deposits and / or disinfectant residue deposits HF arcing may occur in the area of the button.
- ◇ It is therefore particularly important to manually pre-clean the working elements with passive cutting action (cutting is carried out by spring pressure):
  - ◆ Electrode lock
  - ◆ Holder for electrode and
  - ◆ Spring

- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Brush in the area of the electrode lock and of the receptacle.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.

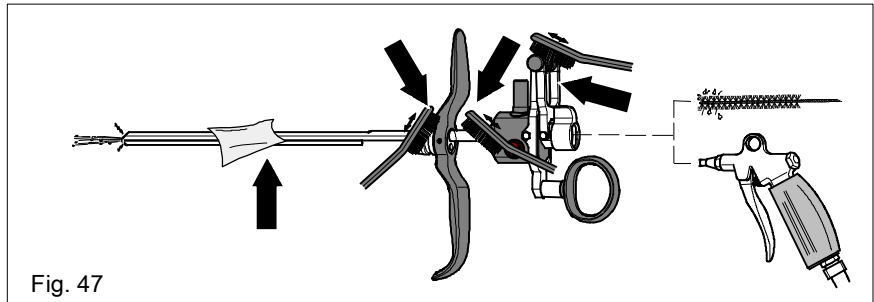


Fig. 47

## 6.2.2.4 HF instruments / electrodes

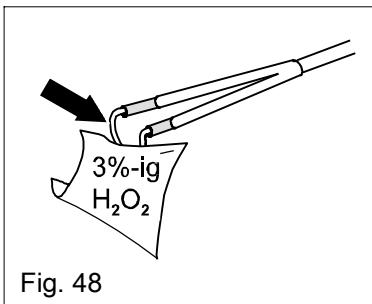


Fig. 48

**Fig. 48**

- ◇ Example:
  - ◆ Cutting electrode
- ◇ Dissolve encrustations with a 3% hydrogen peroxide solution (H<sub>2</sub>O<sub>2</sub> solution).
- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Remove dissolved residues with a suitable cleaning brush or a lint-free disposable cloth.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.

## 6.2.3 Access instruments

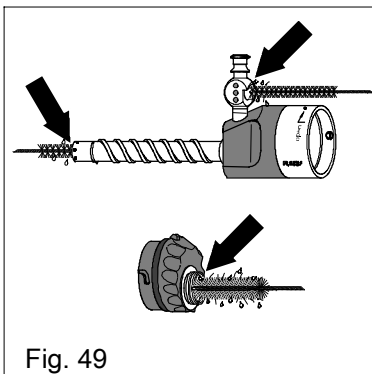


Fig. 49

### Maintenance-free stopcocks

**Fig. 49**

- ◇ Example:
  - ◆ Trocar sleeve
- ◇ For cleaning of stopcocks see Fig. 38 / Fig. 39.
- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Clean hollow spaces with suitable cleaning brushes.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.

## Manual reprocessing

### 6.2.3.1 Instruments with hollow spaces / channels

**Fig. 50**

- ◇ Examples:
  - ◆ Cannula
  - ◆ Dilator
- ◇ Immerse the instruments in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Clean the hollow spaces / channels with a syringe filled with cleaning solution.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with a dry syringe and outside with a lint-free disposable cloth or swab.
- ◇ Check patency (free passage) of small diameter cannulas using a guide wire or cleaning wire.

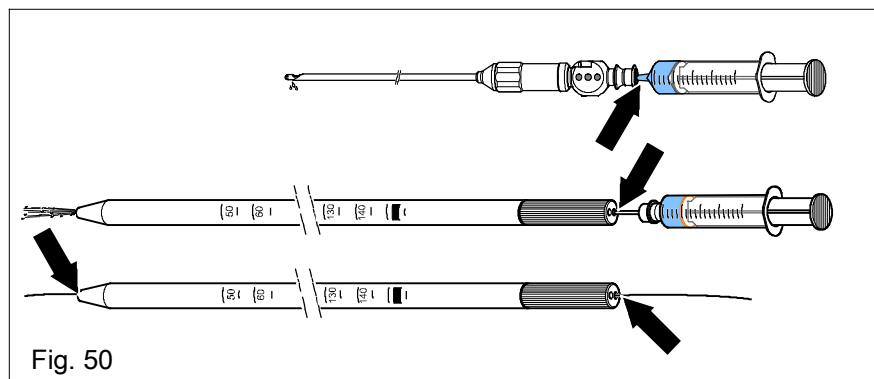


Fig. 50

### 6.2.4 Accessories



**CAUTION!**

*Do not clean the following optical and electrical accessories in an ultrasonic bath:*

- ◆ *Fiber light cables and fluid light cables*
- ◆ *Objective lenses, camera heads and camera cables*
- ◆ *HF monopolar / bipolar connection cables*

#### 6.2.4.1 Mechanical

- ◇ Example:
  - ◆ Reprocessable tubes / hoses
- ◇ Immerse hoses and tubes in a certified cleaning solution for at least 5 min and fill inside.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry inside with compressed air and outside with a lint-free disposable cloth or swab.



**IMPORTANT!**

*To guarantee effective steam sterilization, the tubes must be dry.*

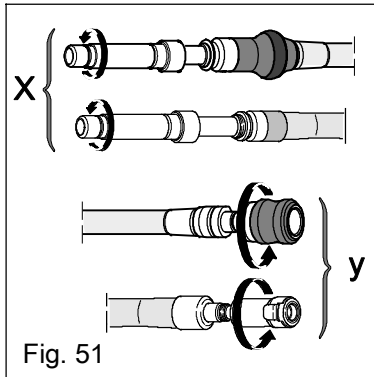


**IMPORTANT!**

*Do not reprocess disposable tube systems (see section 1.7).*

## Manual reprocessing

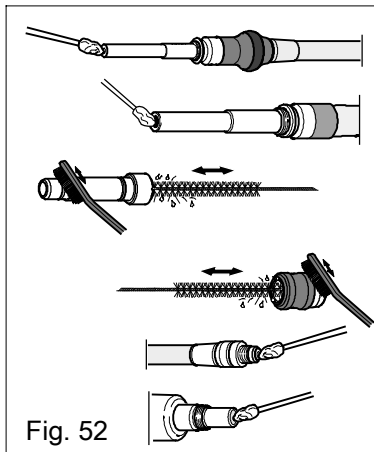
### 6.2.4.2 Optical



- ◇ Examples:
  - ▶ Fiber light cable

**Fig. 51**

- ◇ Remove the adapters between the projector and the light cable (x) and between the light cable and the endoscope (y).



**Fig. 52**

- ◇ Immerse the fiber light cables in a certified cleaning solution for at least 5 min and wipe.
  - ▶ Exposure time as specified by the manufacturer
- ◇ Clean adapter with suitable cleaning brushes.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry the outside surfaces with a lint-free disposable cloth or swab.
- ◇ If cleaning **is not** followed by disinfection, clean the light entry and light exit surfaces with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).

- ◇ Examples:
  - ◆ Objective lenses and camera heads

 **IMPORTANT!**

*Do not expose the camera head with camera cable and plug to temperatures above **maximum 65° C**.*

A contaminated camera plug must be reprocessed manually before installing the protection cap.

- ◇ Immerse the camera plug in a certified compatible cleaning and disinfectant solution.
- ◇ Then rinse with sterile water.
- ◇ Dry the outer surfaces with a sterile lint-free disposable cloth, dry the contacts inside with a swab.
  - ◆ Residual moisture in the contacts can impair signal transmission (e.g. interruptions, poor contacts).

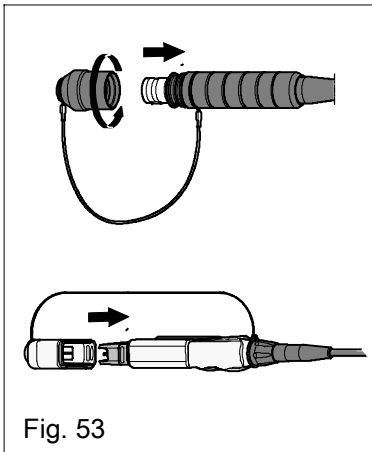
**Fig. 53**

- ◇ Screw or plug the protection cap onto the camera plug.

 **IMPORTANT!**

*Reprocess the camera plug only with the protective cap in place !*

*If inadvertently liquid enters into the camera plug (e.g. due to a forgotten protection cap), rinse the plug briefly with clear water and dry carefully (with compressed air if necessary).*



**Fig. 53**

- ◇ If possible separate the objective lens from the camera head.
- ◇ Immerse the camera head in a certified cleaning solution for at least 5 min.
  - ◆ Exposure time as specified by the manufacturer
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry the outside surfaces with a lint-free disposable cloth or swab.
- ◇ If cleaning **is not** followed by disinfection, clean the glass surfaces with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).

## 6.2.4.3 Electrical

- ◇ Examples:
  - ◆ HF monopolar / bipolar connection cables
- ◇ Immerse HF monopolar / bipolar connection cables in a certified cleaning solution for at least 5 min and wipe.
- ◇ Then thoroughly re-rinse with fully demineralized water.
- ◇ Dry the inside of the plug with compressed air and the outside with a lint-free disposable cloth or swab.

## Manual reprocessing

### 6.3 Ultrasonic cleaning

#### 6.3.1 Cleaning in the ultrasonic bath

When using an ultrasonic bath for cleaning observe the following:

- ◇ Use a certified compatible cleaning agent or a cleaning disinfectant.
- ◇ Change the certified cleaning solution at regular intervals - at least once a day.
  - ◆ High contamination load in the ultrasonic bath impairs the cleaning effect and increases the risk of corrosion.
- ◇ Place instruments only in the dedicated baskets.
- ◇ Place instruments with hollow spaces / channels in such a way that no air is trapped.
- ◇ The instruments must be completely covered by the certified cleaning solution.
  - ◆ Observe the fill level specified by the device manufacturer.
- ◇ Fasten the instruments avoiding contact points with other instruments to avoid damage.
- ◇ Avoid sound shadows.
- ◇ Do not overload the ultrasonic bath.



#### **IMPORTANT!**

*Ultrasonic cleaning may increase hair cracks on coated instruments.*

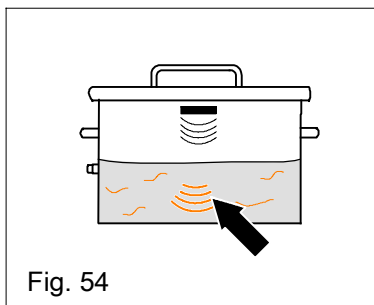


Fig. 54

#### **Fig. 54**

- ◇ In agreement with the certified cleaning and disinfectant solution, adhere to the following cleaning times:
  - ◆ Sound exposure time 3 - 5 min
  - ◆ Frequency 35 - 40 kHz
  - ◆ Temperatures maximum 45°C
    - Temperatures above 50°C can cause blood encrustations.

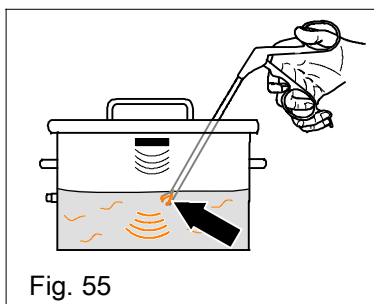


Fig. 55

#### **Fig. 55**

In the case of hard-to-remove residues, e.g. on joint parts

- ◇ hold the instrument tip in the ultrasonic bath and move it around.
- ◇ Place articulated instruments into the ultrasonic bath only in open condition.
  - ◆ Use RICHARD WOLF cleaning clamps if necessary.
  - ◆ See section 11 "Accessories for reprocessing".

#### 6.3.2 After ultrasonic cleaning

- ◇ To remove cleaning agent and disinfectant residues, thoroughly rinse the instruments manually with fully demineralized water.
- ◇ Dry the inside with compressed air and the outside with a lint-free disposable cloth or swab.



#### **IMPORTANT!**

*On articulated instruments with irrigation connector, reattach the luer lock cap only after sterilization.*

## Manual reprocessing

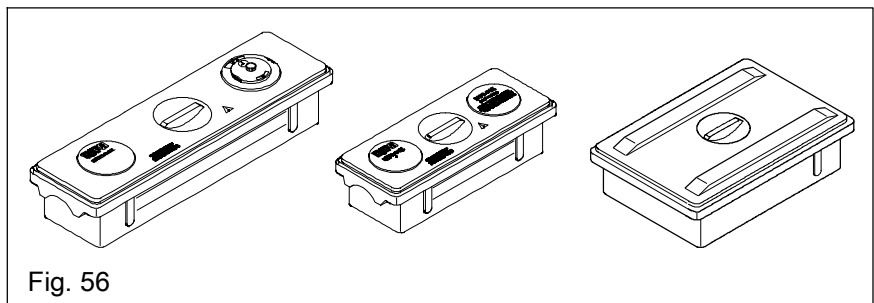
### 6.4 Disinfection

- ◇ For manual disinfection, immerse all parts in a certified disinfectant solution. Follow the disinfectant manufacturer's instructions with regard to
  - ◆ Disinfection efficacy
  - ◆ Concentration
  - ◆ Immersion time / exposure time and
  - ◆ Use life

#### 6.4.1 RIWO BOX SYSTEM

**Fig. 56**

- ◇ For 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.
  - ◆ Thanks to the inclined bottom of the sieve basket even small diameter instruments can be completely filled, avoiding the risk of creating air bubbles in the hollow spaces or channels.
  - ◆ The RIWO BOX is also available as a steam sterilizable version.



- ◇ To avoid mechanical damage, immerse telescopes and instruments separately in the certified disinfectant solution.
- ◇ Immerse O-rings, sealing caps and rubber caps and seals separately.
- ◇ Open maintenance-free stopcocks.
- ◇ Immerse stopcocks with removable plugs in disassembled condition.

#### 6.4.2 After disinfection

- ◇ Rinse all parts with sterile water avoiding any residues.
- ◇ Dry inside with filtered compressed air and outside with a sterile lint-free disposable cloth or swab.

#### 6.4.3 Accessories

##### 6.4.3.1 Mechanical

- ◇ Example:
  - ◆ Reprocessable tubes / hoses
- ◇ Immerse tubes and hoses in a certified disinfectant solution.
  - ◆ For the concentration and exposure time of the disinfectant used please refer to the chemical manufacturer's instructions.
- ◇ Fill the inside with disinfectant (e.g. using a syringe).
- ◇ Then rinse out with sterile water avoiding any residues.
- ◇ Dry inside with filtered compressed air and outside with a sterile lint-free disposable cloth or swab.



## Manual reprocessing

### 6.4.3.2 Optical

- ◇ Examples:
  - ◆ Fiber light cable / fluid light cable
- ◇ Immerse the light cable in a certified disinfectant solution.
  - ◆ For the concentration and exposure time of the disinfectant used please refer to the chemical manufacturer's instructions.
- ◇ Then rinse out with sterile water avoiding any residues.
- ◇ Dry the outside surfaces with a sterile lint-free disposable cloth or swab.
- ◇ Clean the light entry and light exit surfaces with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).
  
- ◇ Examples:
  - ◆ Objective lenses and camera heads
- ◇ Immerse objective lenses and camera heads in a certified disinfectant solution.
  - ◆ For the concentration and exposure time of the disinfectant used please refer to the chemical manufacturer's instructions.
- ◇ Then rinse with sterile water avoiding any residues.
- ◇ Dry the outside surfaces with a sterile lint-free disposable cloth or swab.
- ◇ Clean the glass surfaces with a sterile cotton swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol (ethanol, isopropanol).

### 6.4.3.3 Electrical

- ◇ Examples:
  - ◆ HF monopolar / bipolar connection cables
- ◇ Immerse HF monopolar / bipolar connection cables in a certified disinfectant solution.
  - ◆ For the concentration and exposure time of the disinfectant used please refer to the chemical manufacturer's instructions.
- ◇ Then rinse with sterile water avoiding any residues.
- ◇ Dry electrical connections / plugs with filtered compressed air and, outside, with a sterile lint-free disposable cloth or swab.

### 6.4.4 Reprocessing material

- ◇ Example:
  - ◆ Cleaning brushes
- ◇ Immerse cleaning brushes in a certified disinfectant solution.
  - ◆ For the concentration and exposure time of the disinfectant used please refer to the chemical manufacturer's instructions.
- ◇ Then rinse with sterile water avoiding any residues.
- ◇ Dry outside with a sterile lint-free disposable cloth or swab.

## Checking and maintenance

### 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 products for the following:

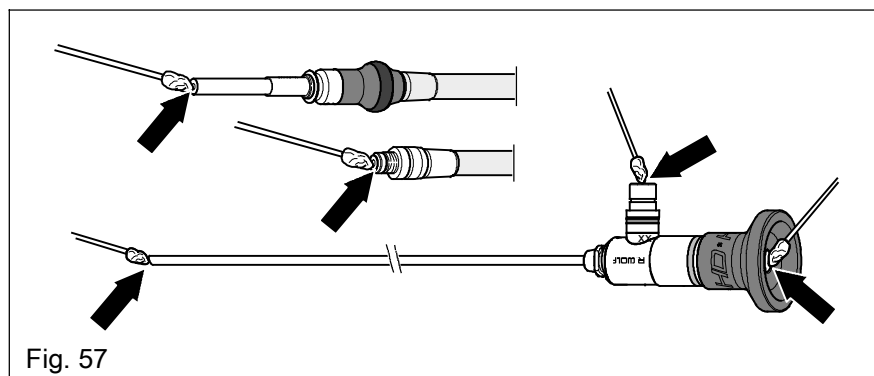
- ◇ Damage
- ◇ Sharp edges
- ◇ Loose or missing parts
- ◇ Rough surfaces
- ◇ Any lettering, labeling or identification necessary for the safe intended use must be legible.
  - ◆ Missing, illegible inscriptions and identifications leading to wrong handling and reprocessing must be reinstated.
- ◇ Cleaning agent and disinfectant residues.
  - ◆ Remove any residues.
- ◇ Check products with lumens / channels and hollow spaces for patency (free passage).
  - ◆ Rework clogged products.
  - ◆ Replace the products if there is no patency (free passage of the channels).

#### 7.1.1 Telescopes / optical accessories

- ◇ Examples:
  - ◆ Telescopes
  - ◆ Fiber light cable

**Fig. 57**

- ◇ Check the glass surfaces for any 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 sterile swab (wooden swab carrier, not metal or plastic) soaked with 70% alcohol, wipe off hard-to-remove deposits with a suitable instrument cleaner.

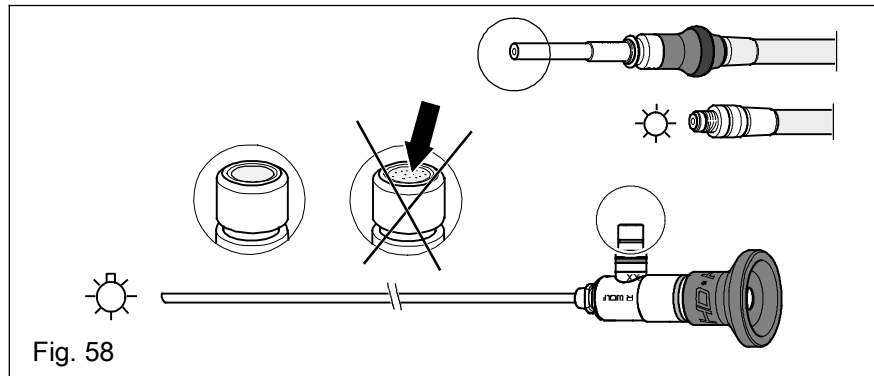


## Checking and maintenance

- ◇ Check image quality and light output.

**Fig. 58**

- ◇ Hold the distal end of the telescope 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.



**IMPORTANT!**

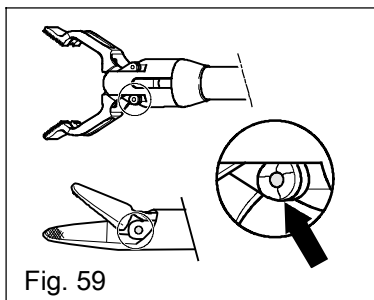
*If you cannot remove the deposits, send in the products for repair.*



**IMPORTANT!**

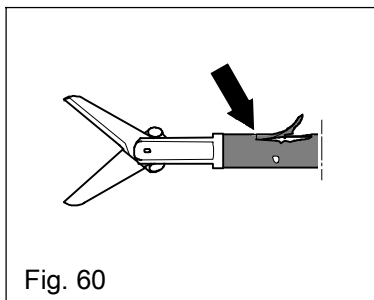
*Regular cleaning with alcohol after reprocessing avoids deposits.*

### 7.1.2 Working instruments



**Fig. 59**

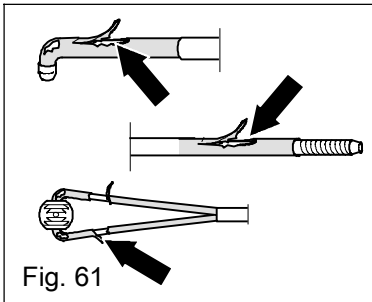
- ◇ Examples:
  - ◆ Forceps, scissors, punches
- ◇ Check the hinge and hinge pin area with particular care. Check for surface changes, such as hair cracks at the hinge pin.
- ◇ Check the jaw sections for proper cutting as required for the application.



**Fig. 60**

- ◇ Examples:
  - ◆ Modular forceps and scissors system "RIWO GRIP" / "modu line"
  - ◆ HF instruments / electrodes
- ◇ Check insulation for damage (e.g. cracks, bending).

## Checking and maintenance



**Fig. 61**

- ◇ Examples:
  - ◆ HF instruments / electrodes
- ◇ Check insulation for damage (e.g. cracks, bending).

**Fig. 62**

- ◇ Example:
  - ◆ Resectoscope sheath with distal ceramic insulation
- ◇ Check the ceramic insulation at the distal end of the resectoscope sheath for damage before every use.



**WARNING!**

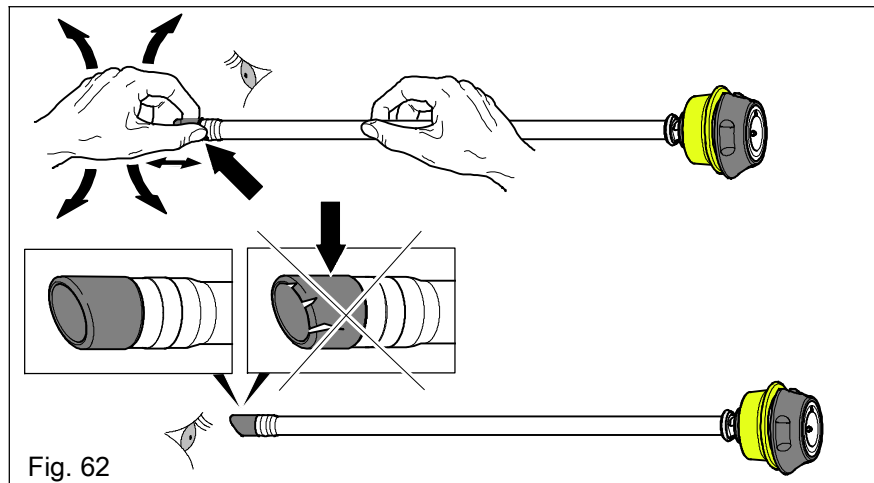
**Danger of injury!**

*Wrong handling, e.g. if dropped, impacted or damaged by similar mechanical loads can cause hair cracks and / or spalling of ceramic material in the distal area of the resectoscope sheath.*

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

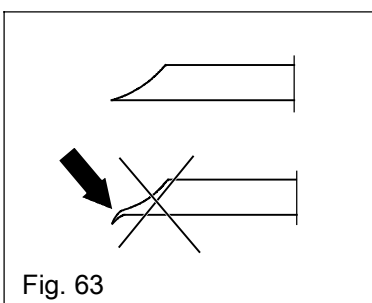
*Observe surface changes and ensure safe handling.*

*Do not use damaged resectoscope sheaths, return damaged sheaths for repair.*



**Fig. 62**

### 7.1.3 Access instruments



**Fig. 63**

**Fig. 63**

- ◇ Examples:
  - ◆ Cannulas
  - ◆ Products with small sheath diameter
- ◇ Check the products for damage (e.g. bending, blunt tip).

## Checking and maintenance

### 7.1.4 Accessories

#### 7.1.4.1 Mechanical

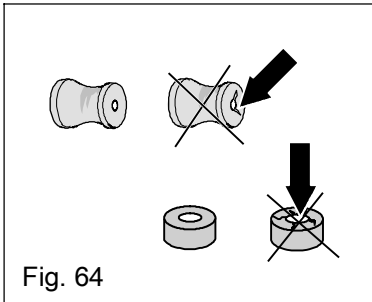


Fig. 64

**Fig. 64**

- ◇ Examples:
  - ◆ Sealing caps and rubber caps
- ◇ Check the products for damage (e.g. cracks, brittleness).

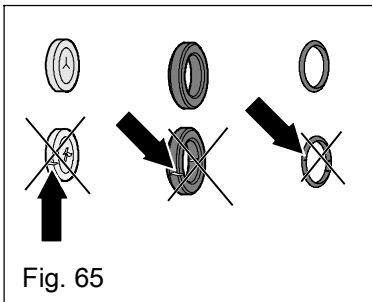


Fig. 65

**Fig. 65**

- ◇ Examples:
  - ◆ O-rings / seals
- ◇ Check the products for damage (e.g. cracks, brittleness).

- ◇ Example:
  - ◆ Reprocessable tubes / hoses
- ◇ Check the products for damage (e.g. cracks, brittleness and tightness).

#### 7.1.4.2 Optical

**Fig. 66**

- ◇ Examples:
  - ◆ Camera cable
  - ◆ Fiber light cable
- ◇ Check the external coating of the cable for damage (e.g. cracks, kinks).
- ◇ Check the projector-to-light-cable (x) and light-cable-to-endoscope (y) adapters for damage.

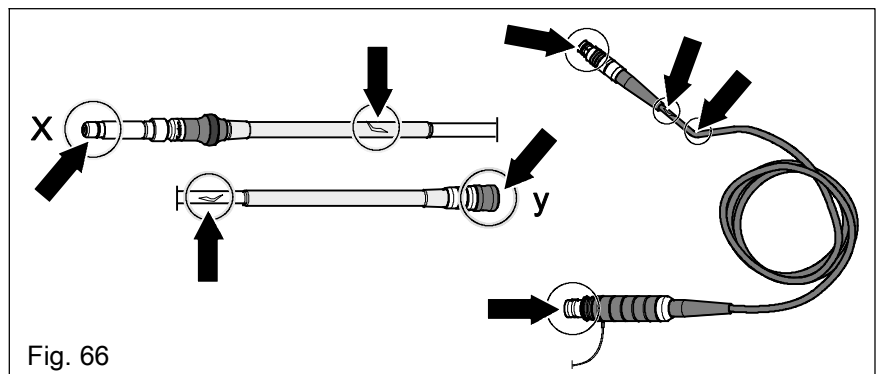


Fig. 66

## Checking and maintenance

### 7.1.4.3 Electrical

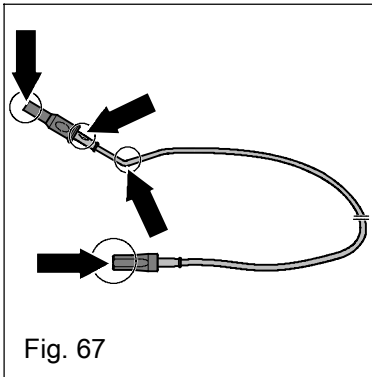


Fig. 67

**Fig. 67**

- ◇ Examples:
  - ◆ HF monopolar, bipolar connection cables
- ◇ Check the products for damage (e.g. cracks, kinks).
- ◇ Replace the products if one the following is observed:
  - ◆ Cable fracture / parted cable
  - ◆ Damaged external coating (insulation)
  - ◆ Corroded connectors

### 7.2 Function check

- ◇ Carry out a function check.
  - ◆ See product-specific instructions for use

## Checking and maintenance

### 7.3 Notes and instructions on maintenance before sterilization

- ◇ Assemble the instruments if necessary.
  - ◆ See product-specific instructions for use

**NOTE!**

*Before sterilization, screw on the screw connections only loosely in order*

- ◆ *to allow a sufficient flow of the sterilization medium.*
- ◆ *to prevent stress cracks.*

*Tighten all screw connections before use.*

Fig. 68

**IMPORTANT!**

*Do **not** apply spray oil to the products and accessories to prevent resinification.*

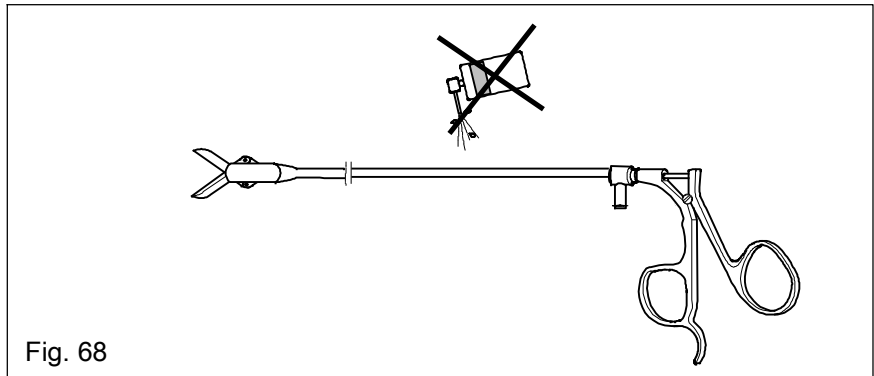


Fig. 68

#### 7.3.1 Working instruments

- ◇ Sparingly oil movable parts with instrument oil (200.532).
  - ◆ Wipe off any excess instrument oil using a lint-free disposable cloth.
- ◇ Check for easy operation.

**Fig. 69**

- ◇ Examples:
  - ◆ Forceps, scissors, punches
  - ◆ Working inserts with Albarran lever

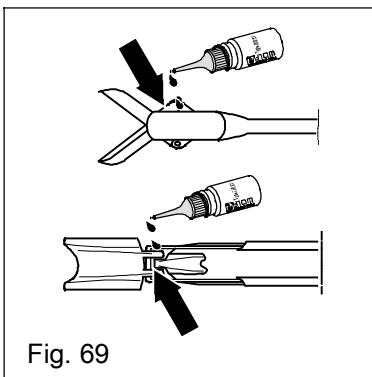
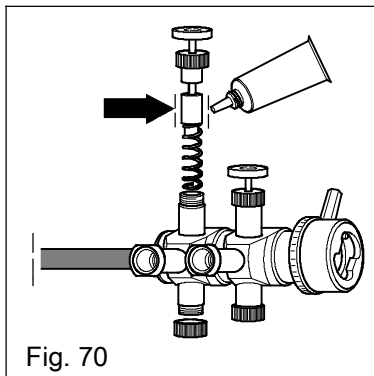


Fig. 69

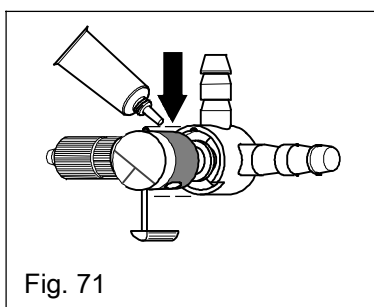
## Checking and maintenance

- ◇ Sparingly grease the moveable parts with Instrument Grease 20012.
  - ◆ Wipe off any excess instrument grease using a lint-free disposable cloth.
- ◇ Check for easy operation.



**Fig. 70**

- ◇ Example:
  - ◆ Suction and irrigation tubes with trumpet valve

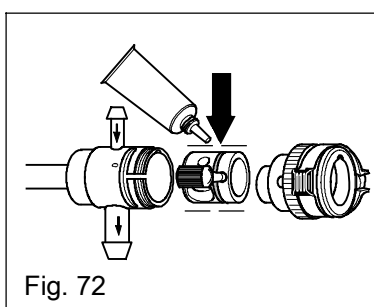


**Fig. 71**

- ◇ Examples:
  - ◆ Rotatable stopcocks
- ◇ Sterilize in disassembled condition.

### 7.3.2 Access instruments

- ◇ Sparingly grease the moveable parts with Instrument Grease 20012.
  - ◆ Wipe off any excess instrument grease using a lint-free disposable cloth.
- ◇ Check for easy operation.



**Fig. 72**

- ◇ Examples:
  - ◆ Resectoscope sheaths with central stopcock
- ◇ Sterilize in disassembled condition.

- ◇ Further notes on checks and maintenance
  - ◆ See product-specific instructions for use



## 8 Sterilization

The safest way to kill microorganisms is a thermal procedure.

In the discipline of "Rigid Endoscopy", RICHARD WOLF recommends using steam sterilization with pre-vacuum, e.g. in accordance with DIN EN 285 / ISO 14937 if possible.

Gas sterilization and other additional methods neither reach the sterilization safety of steam sterilization nor the quality of process control and monitoring.



### **CAUTION!**

#### **High thermal load!**

**To avoid damage to the rigid telescopes and endoscopic accessories as a result of the high thermal load, do not sterilize using hot air.**



### **IMPORTANT!**

The instructions listed in section 1.10 "**Overview of reprocessing / material compatibility**" have been released by RICHARD WOLF for the reprocessing of a medical product for the purpose of its 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.

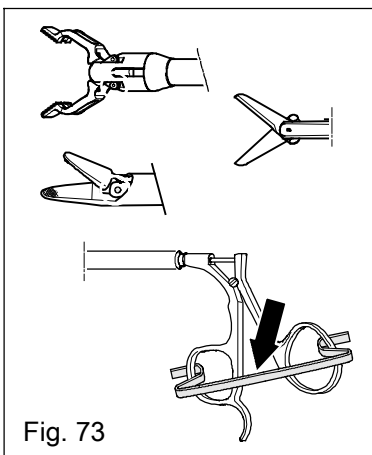
This requires validations and routine monitoring of the procedures. Any deviation from the instructions provided should be carefully evaluated by the reprocessor for efficacy and possible unfavorable results.



### **IMPORTANT!**

Please observe the following regarding sterilization:

- ◇ For sterilization the products must be sufficiently clean and dry.



**Fig. 73**

- ◇ Sterilize forceps, scissors and punches only in open condition.
  - ◆ Heating and cooling phases during sterilization induce stresses in the material which may cause cracks in the hinge area or reduced gripping power.
- ◇ In the case of self-closing forceps, place a cleaning clamp into the forceps handles.
- ◇ The sterilization packaging (wrapping) must take into account the contents of the package as well as the sterilization method to be used.
- ◇ Pack / wrap the rubber caps and sealing caps and seals, if applicable, together with the instruments and install again after sterilization and before use.
  - ◆ See product-specific instructions for use

### 8.1 Auxiliary resources required

- ◇ Storage systems for sterilization
  - ◆ See section 11 "**Reprocessing of accessories**".
- ◇ Depending on the sterilization method: suitable sterilizer
  - ◆ Preferably steam sterilizer to DIN EN 285 / ISO 14937
  - ◆ Follow the notes and instructions / the manual of the sterilizer manufacturer.
- ◇ Sterile packaging / wrapping
  - ◆ Follow the national and international standards

# Sterilization

## 8.2 Steam sterilization

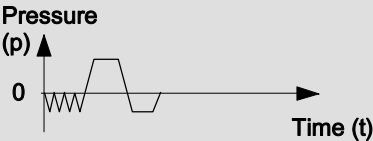
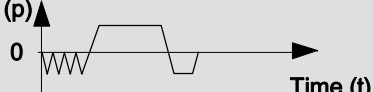
Also with regard to process validation the fractional pre-vacuum procedure is currently the safest steam sterilization method. RICHARD WOLF products have been tested with the fractional pre-vacuum method.

 **IMPORTANT!**

- ◇ *The steam used for sterilization must not contain any contaminants.*
  - ◆ *Observe national / international standards, such as DIN EN 285 / ISO 14937. If these standards are not adhered to, it is possible e.g. that*
    - ◆ *rust particles from the water supply cause corrosion on the instruments or*
    - ◆ *an excessively high silica content causes discolorations on the instruments.*
- ◇ *Do not expose telescopes to sudden changes in temperature.*
  - ◆ *Allow the container with the telescopes to slowly cool down to hand warmth.*
- ◇ *The temperature must not exceed 138° C.*

### 8.2.1 Overview of steam sterilization procedures

#### 8.2.1.1 Fractional pre-vacuum procedure

Designation	Description	Use
Fractional pre-vacuum procedure to DIN EN 285 RICHARD WOLF test method Example: 	<ul style="list-style-type: none"> <li>◆ Chamber is evacuated then steam is injected (steam shock).</li> <li>◆ Several steam injections and mixture evacuation cycles rarify the air in the chamber quickly and to a very high degree.</li> <li>◆ High pressure differentials generate a very strong forced flow of steam within the material to be sterilized; currently this is therefore the safest method in cases where air can be trapped.</li> <li>◆ Suitable for all standardized methods of single or double packaging / wrapping.</li> </ul>	<ul style="list-style-type: none"> <li>◆ Instruments</li> <li>◆ Telescopes</li> </ul>
Temperature: 134°C +4°C (273°F +7°F) 132°C +4°C (270°F +7°F)	Temperature exposure time: 4 minutes*) Drying time: 10 - 20 minutes	Evacuation: 3 x
<ul style="list-style-type: none"> <li>◆ Fractional pre-vacuum procedure</li> <li>◆ Example:  </li> </ul>	<ul style="list-style-type: none"> <li>◆ See "fractional method at 134°C (273°F).</li> </ul>	<ul style="list-style-type: none"> <li>◆ Instruments</li> <li>◆ Items that withstand 121°C (246°F)</li> </ul>
Temperature: 121°C +3°C (246°F +5°F)		

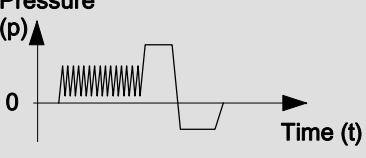
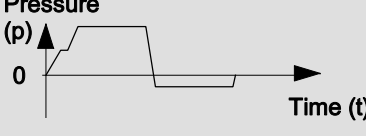
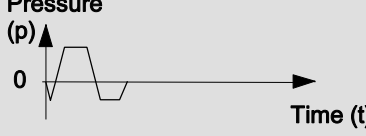

 **IMPORTANT!**

*When using small steam sterilizers to DIN EN 13060 make sure that only type B sterilizers are used. These type B sterilizers are specially designed for hollow parts.*

*\*) If no other temperature exposure times are specified in the product-specific instruction manual, these specifications shall apply.*

## Sterilization

### 8.2.1.2 Other steam sterilization procedures

Designation	Description	Use
<ul style="list-style-type: none"> <li>▶ Fractional flow method</li> <li>▶ Example:</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Process begins with numerous steam shocks at overpressure; during mixture evacuation the pressure does not exceed the ambient pressure.</li> <li>▶ High pressure differentials generate a very strong forced flow of steam within the material to be sterilized - providing high safety against trapped air.</li> <li>▶ Suitable for all standardized methods of single or double packaging / wrapping.</li> </ul>	<ul style="list-style-type: none"> <li>▶ Instruments</li> <li>▶ Telescopes</li> </ul>
Temperature: 134°C +4°C (273°F +7°F)		
<ul style="list-style-type: none"> <li>▶ Flow method</li> <li>▶ Gravity / Displacement</li> <li>▶ Example:</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Steam displaces the air which constantly escapes from the items to be sterilized (which is twice the unit weight) from the chamber.</li> <li>▶ As deaeration is not always complete, enough air remains to make compensation periods necessary.</li> <li>▶ Problems arise when the flow is impeded.</li> </ul>	<ul style="list-style-type: none"> <li>▶ For simple instruments.</li> <li>▶ Items must be suitably packed / wrapped.</li> <li>▶ Reproducibility of physical parameters is only guaranteed under certain conditions.</li> <li>▶ Only partially recommended for reasons of hygiene.</li> <li>▶ Not recommended for telescopes with working channel. Multi-part instruments must be disassembled for sterilization.</li> </ul>
Temperature: 121°C +3°C (246°F +5°F) or 134°C +4°C (273°F +7°F)		
<ul style="list-style-type: none"> <li>▶ Pre-vacuum method</li> <li>▶ Example:</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Simple evacuation of air rarifies the air in the chamber.</li> <li>▶ As the "small-load effect" during the rise time generates large areas of trapped air, the method is not suitable for every item.</li> </ul>	<ul style="list-style-type: none"> <li>▶ For items and packages, from which trapped air can escape quickly.</li> <li>▶ For simple instruments.</li> <li>▶ Not recommended for telescopes with working channel. Multi-part instruments must be dismantled and sterilized as necessary, depending on the validation result.</li> <li>▶ For simple wrapping / packaging</li> </ul>
Temperature: 121°C +3°C (246°F +5°F) or 134°C +4°C (273°F +7°F)		
Designation	Description	Use
<ul style="list-style-type: none"> <li>▶ Flash method</li> <li>▶ Example:</li> </ul> 	<ul style="list-style-type: none"> <li>▶ Sterilization time is between 3 and 10 minutes**)</li> </ul>	<ul style="list-style-type: none"> <li>▶ Only suitable for unwrapped / unpacked items.</li> <li>▶ Safety of sterilization not guaranteed in cavities.</li> <li>▶ For endoscopes without working channel.</li> </ul>
Temperature: 134°C +4°C (273°F +7°F)		

- ◇ Steam sterilize parts made of rubber or special plastic material (indicated in the relevant instruction manual) at 121°C +3°C (246°F +5°F) for 15 - 20 minutes\*\*) using the fractional pre-vacuum method.
- ▶ See product-specific instructions for use

## Sterilization

### 8.2.2 Accessories - information on special products

#### 8.2.2.1 Optical

◇ Example:

- ◆ Objective lenses and camera heads
- ◆ Not all objective lenses and camera heads can be steam sterilized.
  - See section 1.10 "**Overview of reprocessing / material compatibility**"
  - See product-specific instruction manual

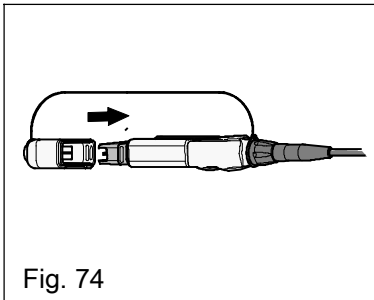


Fig. 74

**Fig. 74**

◇ Example:

- ◆ Steam-sterilizable camera head
  - Sterilize the camera cable only with the protection cap in place.
  - Steam-sterilize the camera head with camera cable and objective lens using the fractional pre-vacuum method at 134°C (273°F).

### 8.2.3 Assembly after sterilization

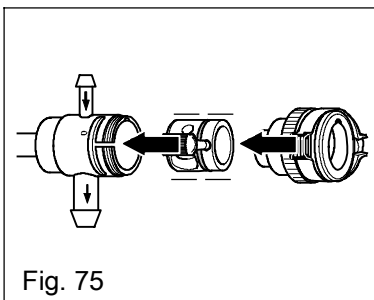


Fig. 75

**Fig. 75**

☞ **IMPORTANT!**

*Assemble the components greased with Instrument Grease 20012 after sterilization.*

## Sterilization

### 8.3 Low-temperature sterilization

Use the low-temperature sterilization procedure only for sterile items which due to their heat sensitivity cannot be sterilized using the steam sterilization process.

- ◇ Open the stopcocks (maintenance-free, with removable plugs).
- ◇ Place the instruments into suitable sterilization systems.
  - ◆ See section 11 "Reprocessing accessories".

 **IMPORTANT!**

*RICHARD WOLF has checked and validated the reprocessing procedures described below only with regard to their material compatibility. These procedures have been approved for use in conjunction with rigid telescopes and endoscopic accessories with certain limitations - for this, see the corresponding notes and instructions.*

*Efficacy tests (microbiological examinations) were carried out on worst-case products.*

 **IMPORTANT!**

*Under no circumstances should the low temperature sterilization procedure with hydrogen peroxide (section 8.3.1 / 8.3.2.3), the procedure with steam (section 8.2.1) and the procedure with peracetic acid (section 8.3.3) 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.*

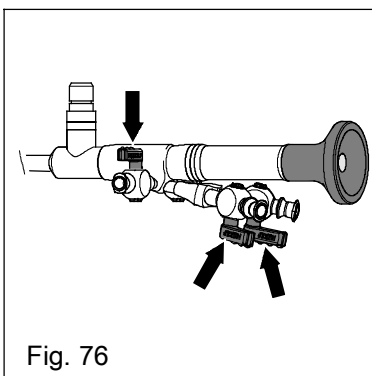
#### 8.3.1 Hydrogen peroxide plasma

 **NOTE:**

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

##### 8.3.1.1 STERRAD® 50 / 100S / 200 / NX™ and 100 NX™

Sterilization validations have been carried out on different products in cooperation with "ASP" (Advanced Sterilization Products) and the "Martin Luther University Halle Wittenberg".



**Fig. 76**

 **NOTE!**

*The efficacy of the STERRAD® 100S procedure in the case of stopcocks with removable plugs has been validated with the stopcocks in assembled and open condition.*

 **NOTE!**

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

[www.sterradsterilityguide.com](http://www.sterradsterilityguide.com)

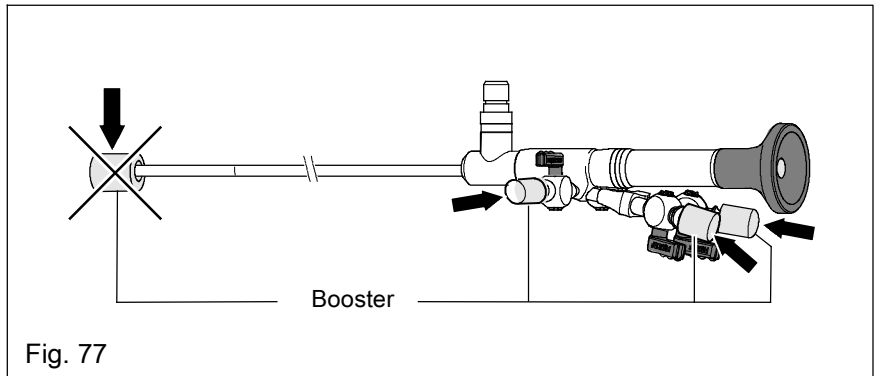
## 8.3.1.2 Sterilizers with Booster / diffusion amplifier in STERRAD® 50 / 100S / 200

**Fig. 77**



**IMPORTANT!**

*Do not plug the booster onto the distal end of the telescope with working channel. The direct effect of the concentrated hydrogen peroxide will damage the bonding points.*



## Sterilization

### 8.3.2 Gas

#### 8.3.2.1 Ethylene oxide gas (EO)

- ◇ Allow instruments to ventilate.

Under ambient conditions ethylene oxide is a gas. Ethylene oxide gas is both toxic and flammable and forms explosive mixtures with air 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.



#### **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 ethylene oxide device manufacturer's instructions.*

#### 8.3.2.2 Low temperature steam and formaldehyde (LTSF)

Sterilization with formaldehyde is an alternative to sterilization with ethylene oxide. Compared to the ethylene oxide procedure, the formaldehyde procedure offers a number of advantages:

- ◆ The formaldehyde water vapor mixture is neither flammable nor explosive.
- ◆ When the sterilization cycle is completed the products can be reused without any further aeration time.

#### 8.3.2.3 Hydrogen peroxide (V-PRO™ 1)

Another alternative procedure is sterilization using hydrogen peroxide. Material compatibility has been tested with this procedure. For efficacy verifications, please observe the information provided by the sterilizer manufacturers.

## Sterilization

### 8.3.3 Peracetic acid / High Level Disinfection

#### 8.3.3.1 STERIS SYSTEM 1® / STERIS SYSTEM 1E™

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

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



**CAUTION!**

*Recontamination of products!*

*These products are not packed sterile.*

*The sterilized products must be used immediately after the end of the sterilization process to avoid recontamination.*



**NOTE!**

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

◆ *Follow the sterilizer manufacturer's instructions.*

◆ *Use the special STERIS rinsing sets for this purpose.*

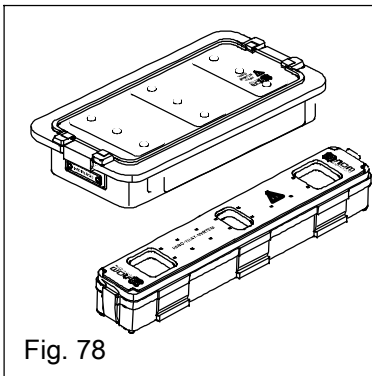
### 8.4 Storage systems for sterilization

◇ Place the instruments into the designated storage systems.

◆ See section 11 "**Reprocessing accessories**".

◇ Wrap / package the storage systems in a sterilization packaging in accordance with the national (e.g. DIN 58953) or international standards.

#### 8.4.1 RIWO SYSTEM TRAY



**Fig. 78**

◇ Example:

◆ RIWO SYSTEM TRAY

#### 8.4.2 Reprocessing baskets

Use product-specific reprocessing baskets.

◇ Example:

◆ See section 5.6.1 "**Telescopes**"

◆ See section 5.6.2 "**Camera heads**"



## 8.4.3 Sterilization sieve basket system

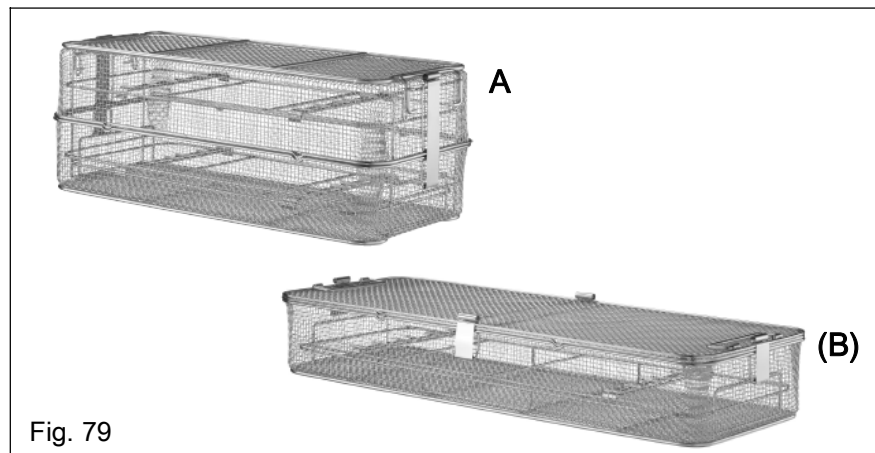
The RICHARD WOLF sieve basket system can be used universally and accommodates the instruments safely and gently during

- ◆ Sterilization
- ◆ Transport
- ◆ Storage

### Fig. 79

◇ Example:

- ◆ Instrument sieve, high (A) / low - standard suitable for a standard container
- ◆ Instrument sieve, high/ low (B) - long e.g. for bronchoscopy, urology (upper urinary tract)



## 8.5 Sterilization of cleaning accessories

- ◇ Steam-sterilize the cleaning brushes and cleaning wires at 134°C (273° F) using the fractional pre-vacuum method.

## Storage and repair

### 9 Storage

#### 9.1 After disinfection

- ◇ Store / keep the products under the following conditions:
  - ◆ Completely dry
  - ◆ Protected from dust
  - ◆ e.g. in a closed drawer / container
  - ◆ Under low microbial conditions

 **IMPORTANT!**

*When storing the instruments over night or for several days, the products must be disinfected again before use.*

#### 9.2 After sterilization

 **IMPORTANT!**

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

- ◇ Store the products in their sterile packaging as follows:
  - ◆ Protected from humidity and changes in temperature
  - ◆ Protected from direct solar radiation
  - ◆ Protected from dust

### 10 Repairs, returned products

 **CAUTION!**

*As we have a duty of care for our staff members in the repair and service department, we must inform you that only products that have been reprocessed according to the state of the art in hygiene can be sent in for repair. If the products to be repaired are visibly soiled or contaminated, we reserve the right to charge the sender for reprocessing.*

 **IMPORTANT!**

*Do not use storage systems for the shipment of products.*

 **NOTE!**

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

11 Accessories for reprocessing

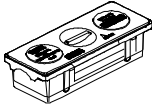
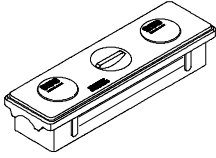
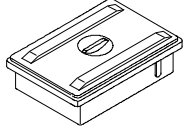
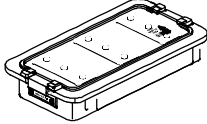

Illustration	Product no.	Designation
<b>DISINFECTION BOXES and STERILIZATION CONTAINERS</b> <b>RIWO BOXES, RIWO SYSTEM TRAYS</b> <b>for manual reprocessing and sterilization</b>		
	<b>6860.901</b>	<b>RIWO BOX</b> for wet decontamination at the point of use, of used and contaminated instruments; Not steam sterilizable incl. sieve basket and lid Outside dimensions: 552 x 200 x 165 mm Inside dimensions of basket: 432 x 150 x 100 mm
	<b>6860.911</b>	<b>RIWO BOX</b> for wet decontamination at the point of use, of used and contaminated instruments; Not steam sterilizable incl. sieve basket and lid Outside dimensions: 881 x 200 x 165 mm Inside dimensions of basket: 760 x 150 x 100 mm
	<b>509.81</b>	<b>RIWO BOX</b> for disinfection; Not steam-sterilizable including lid without lid Outside dimensions: 600 x 400 x 140 mm Inside dimensions: 548 x 348 x 100 mm
	<b>38201.xxx</b>	<b>RIWO SYSTEM TRAY</b> for sterilization on request
	<b>382032200</b>	<b>Sterisafe® DURO A3 Set Universal H<sub>2</sub>O<sub>2</sub></b> STERRAD® / V-PRO™ 1 <b>consisting of:</b>
	<b>382031003</b>	<b>Sterisafe® DURO A3</b> 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
	<b>382031102</b>	<b>Toolsafe® grid support A3 universal</b>
	<b>382031401</b>	<b>Disposable filter H<sub>2</sub>O<sub>2</sub></b> Pack of 100
	<b>382032300</b>	<b>Sterisafe® DURO A3 Set universal steam</b> Steam (S), ethylene oxide (EO) and Low Temperature Steam and Formaldehyde (LTSF) <b>consisting of:</b>
	<b>382031003</b>	<b>Sterisafe® DURO A3</b> 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
	<b>382031102</b>	<b>Toolsafe® grid support A3 universal</b>
	<b>382031501</b>	<b>Disposable filter S, EO and LTSF</b> Pack of 100

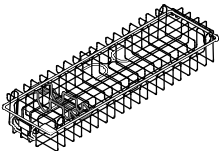
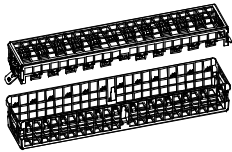
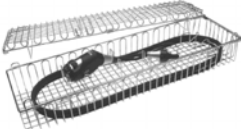
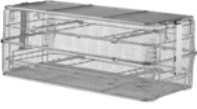
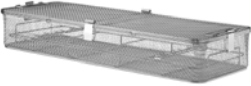





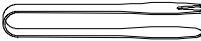

Illustration	Product no.	Designation
<b>ACCESSORIES - STERISAFE® DURO A3</b>		
no illustration	382031401	<b>Disposable filter H<sub>2</sub>O<sub>2</sub></b> Pack of 100
	382031501	<b>Disposable filter S, EO and LTsf</b> Pack of 100
	382031210	<b>Sealing label - steam</b> Pack of 2000
	382031220	<b>Sealing label - H<sub>2</sub>O<sub>2</sub></b> Pack of 500
	382031203	<b>Sterisafe® universal label holder</b>
	382031202	<b>Sterisafe® safety seal</b> Pack of 100
<b>REPROCESSING BASKETS <sup>1)</sup></b> for machine reprocessing and sterilization		
	38010.xxx 38011.xxx 38012.xxx	<b>Reprocessing basket</b> for standard telescopes, accommodates 2 telescopes on request
	38020.111 38021.111 38022.111 38015.001	<b>Reprocessing basket</b> for standard telescopes, accommodates 1 telescope on request L x W x H 287 mm x 59 mm x 54 mm L x W x H 471 mm x 59 mm x 54 mm L x W x H 610 mm x 59 mm x 54 mm <b>Ball chain</b> Pack of 20
	38044.511	<b>Reprocessing basket</b> for camera heads (5509912, 5509972, 85509902, 85509962) L x W x H 472 mm x 132 mm x 74 mm
without illustration	38011.501 38045.111	<b>Reprocessing basket</b> for transducer for URS, miniature nephroscope
	38043012	<b>Reprocessing basket</b> for TEM stereo telescope and documentation telescope 884080 including holding brackets L x W x H 458 mm x 196 mm x 138.5 mm
	38043.011	<b>Reprocessing basket</b> for TEM telescopes incl. holding brackets stereo telescope 4840.501 and documentation telescope 8840.401 L x W x H 458 mm x 196 mm x 138.5 mm


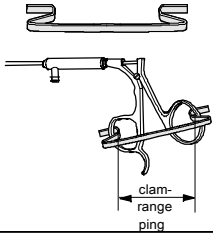





Illustration	Product no.	Designation
<b>REPROCESSING BASKETS 1)</b> for machine reprocessing and sterilization		
without illustration	<b>38044.311</b>	<b>Reprocessing basket</b> for hysteroscope with exchangeable sheath
	<b>38044.111</b>	<b>Reprocessing basket</b> for hysteroscopes, discoscopes and MR-endoscope
	<b>38044.211</b>	<b>Reprocessing basket</b> for mini-laparoscope
<b>STERILIZATION CONTAINER</b> Sterilization sieve basket system 2) for sterilization, transport and storage		
	<b>8584.1202</b>	<b>Sterilization sieve basket system</b> Instrument sieve, high - standard
	<b>8584.1212</b>	<b>Sterilization sieve basket system</b> Instrument sieve, low - standard
	<b>8584.1302</b>	<b>Sterilization sieve basket system</b> Instrument sieve, high - long
	<b>8584.1312</b>	<b>Sterilization sieve basket system</b> Instrument sieve, low - long
	<b>8584.3003</b>	<b>System basket for small parts 1/8</b> with lid L x W x H     121 x 121 x 35 mm
without illustration	<b>8584.xxxx</b>	<b>Accessories</b> to sterilization sieve basket system
<b>STERILE WATER TREATMENT, ACCESSORIES</b>		
	<b>33100.003</b>	<b>Filter cartridges</b> for sterile water filter system Pack of 3
<b>DISASSEMBLABLE STOPCOCKS</b>		
	<b>896.0001</b>	<b>Stopcock plug, complete</b> Passage 2.5 mm; Identification: 2 pegs Packaging unit = Pack of 5.
	<b>896.0002</b>	<b>Stopcock plug, complete</b> Passage 3.0 mm; Identification: 3 pegs Packaging unit = Pack of 5.
	<b>896.0003</b>	<b>Stopcock plug, complete</b> Passage 4.2 mm; Identification: 4 pegs Packaging unit = Pack of 5.
	<b>38310.0001</b>	<b>Disassembly tool</b>
	<b>886.00</b>	<b>Luer lock tube fitting</b>

For loading the reprocessing basket 1) or sterilization sieve basket 2), respectively, see product-specific

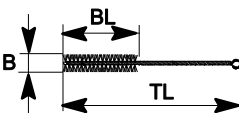
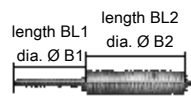
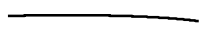

- ◆ Instruction manual for instrument set
- ◆ Instruction manual - reprocessing basket
- ◆ Instruction manual - sterilization sieve basket

Illustration	Product no.	Designation
<b>SEALING CAPS <sup>3)</sup>, RUBBER CAPS "RIWO" <sup>3)</sup></b>		
	<b>89.20</b> <b>89.21</b>	<b>Sealing cap</b> , small / large, without bore, red-orange dia. Ø 15 mm dia. Ø 17 mm Packaging unit = Pack of 10.
	<b>89.xxx</b> <b>90.xxx</b>	<b>Sealing cap</b> small / large, on request dia. Ø 15 mm, passage dia. Ø xx.x - xx.x mm dia. Ø 17 mm, passage dia. Ø xx.x - xx.x mm Packaging unit = Pack of 10.
	<b>89.90</b>	<b>Sealing cap</b> with cross slot, for trocar sleeve with threaded sheath, red-orange, dia. Ø 17 mm Packaging unit = Pack of 10.
	<b>88.xxx</b>	<b>Rubber cap "RIWO"</b> on request Passage Ø x.x mm Packaging unit = Pack of 10.
	<b>18.01</b>	<b>Rubber cap</b> for hysteroscope, extended
<b>CLEANING ACCESSORIES</b>		
	<b>6199.00</b>	<b>Cleaning gun</b> water jet, for tap connection with R-3/4" thread incl. adapters (A - H, see below) and holder  The adapters are suitable for cleaning the following
	<b>15515.003</b>	<b>A</b> Sheaths and inserts, syringes, injection cannulas
	<b>15515.004</b>	<b>B</b> Sheaths, measuring and blood pipettes
	<b>15515.005</b>	<b>C</b> Catheters
	<b>15515.006</b>	<b>D</b> Drainage hoses / tubes
	<b>15515.007</b>	<b>E</b> Stopcocks, cannulas, syringes
	<b>15515.009</b>	<b>F</b> Sprinkler adapters
	<b>15515.008</b>	<b>G</b> Bottles
	<b>15515.010</b>	<b>H</b> Water jet pumps (with adapters also suitable for drying)
	<b>103.00</b>	<b>Rubber bulb</b> for blowing air through the channels
	<b>127.00</b>	<b>Double bulb with Luer fitting 886.00</b> for blowing air through the channels

<sup>3)</sup> see product-specific instructions for use or latest catalog sheets

Illustration	Product no.	Designation
<b>CLEANING ACCESSORIES</b>		
	<b>8201.50</b>	<b>Instrument holding forceps</b> distally angled, with rubber jaws for gentle, careful holding of instruments
without illustration	<b>8201.501</b>	<b>Spare rubber jaws</b> for instrument grasping forceps Packaging unit = 2 / pkg.
	<b>103.01</b>	<b>Cleaning clamp</b> for forceps handles, short clamping range: up to 75 mm Packaging unit = Pack of 10.
	<b>103.02</b>	<b>Cleaning clamp</b> for forceps handles, long clamping range: from 75 to 110 mm Packaging unit = Pack of 10.
	<b>15242.024</b>	<b>Cleaning clamp</b> for working element
<b>CLEANING AND CARE PRODUCTS</b>		
	<b>200.532</b>	<b>Instrument oil</b> Contents: 30 ml for trocar sleeves, resectoscopes, stopcocks as well as flexible and rigid forceps
	<b>20012</b>	<b>Instrument grease</b> 10 ml tube, steam-sterilizable
	<b>102.02</b>	<b>Anti-fogging agent</b> for endoscopes, disposable Packaging unit = Pack of 10.
	<b>200.00</b>	<b>Oil syringe</b> (empty)

# Accessories

Illustration	Product no.	Designation						
		CLEANING BRUSHES / CLEANING WIRE						
		Brush dia. Ø [mm]			Brush length [mm]			Total length [mm]
		B	B1	B2	BL	B1	B2	TL
		<i>Application example</i>						
	6.01	11	-	-	100	-	-	360
	<i>Sheaths and trocar sleeves</i>							
	6.03	5	-	-	50	-	-	375
	<i>Telescope guide tubes on working elements (feeders)</i>							
	6.04	2	-	-	50	-	-	400
	<i>Electrode guide tubes on working elements (feeders)</i>							
	6.041	3	-	-	50	-	-	365
	6.045	2	-	-	50	-	-	240
	6.05	5	-	-	60	-	-	515
	<i>Operating laparoscopes</i>							
	6.06	5	-	-	50	-	-	240
	<i>Small-caliber sheaths (240 mm long)</i>							
	6.061	1.8	-	-	55	-	-	610
	6.07	13	-	-	80	-	-	340
	<i>Rectoscope tubes for children</i>							
	6.08	19	-	-	80	-	-	440
	<i>Rectoscope tubes</i>							
	6.09	9	-	-	80	-	-	405
6.12	12	-	-	100	-	-	700	
6.20	20	-	-	100	-	-	620	
<i>Esophagoscope tubes, depending on dimension</i>								
	6.011	-	3	5	-	40	100	250
	6.012	-	3	13	-	40	100	250
	on request	-	-	-	-	-	-	xxx
	6.24	5	-	-	10	-	-	2200
	6.40	8	-	-	12	-	-	2200
	6.70	12	-	-	20	-	-	2350
	86.90	-	-	-	42	-	-	147



## 12 Product information on cleaning and care products



### **NOTE 1**

*RICHARD WOLF instrument oil is neither a hazardous substance nor a hazardous preparation according to EC directive 88 / 379 / EEC article 10.*

*Pursuant to 91 / 155 EEC, no special information system (safety data sheet) is therefore required.*

### 12.1 Instrument oil 200.532

#### 12.1.1 Product description

The product is a care oil based on medicinal white oil. The product serves to maintain the functionality and preserve the value of the instrument.

#### 12.1.2 Field of use

Thanks to its outstanding material compatibility this product can be used without any limitations on oil-resistant heat-stable instruments as well as on metal parts of heat-sensitive instruments.

- ◇ Reprocess the instruments before applying instrument oil.
  - ◆ Follow the product-specific instruction manual.
- ◇ After applying instrument oil, check the instruments for proper functioning and sterilize according to the instructions.

#### 12.1.3 Additional notes and instructions for use



### **CAUTION!**

***Do not use this product on non-oil-resistant instruments.***

- ◇ Apply the product sparingly onto the corresponding parts to achieve sufficient lubrication.
- ◇ Remove any excess product with suitable lint-free and hygienic fiber cloths.

#### 12.1.4 Product specifications

##### **Appearance:**

- ◆ The product is oily, as clear as water, almost odorless and tasteless.

##### **Ingredients:**

- ◆ Medicinal white oil.

##### **Ingredient specification:**

- ◆ Medicinal white oil in accordance with the purity requirements to DAB 10, Pharm.
- ◆ Europ. (Ph. Eur. 2nd Ed), BP 1993, USP XXII, NF XVII, FDA 172.878

##### **Physical / chemical properties:**

- ◆ Density (15 °C): 0.84 - 0.86 g/cm<sup>3</sup>
- ◆ Viscosity (20 °C): 15.5 - 18.5 mm<sup>2</sup>/s
- ◆ Boiling point: 280 °C

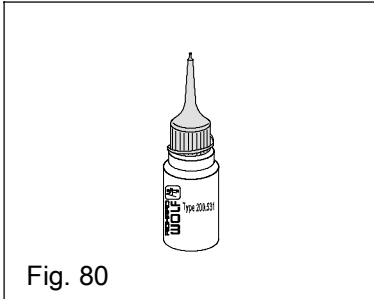
**Manufacturing specification:**

- ◆ The product is manufactured and filled in accordance with approved written work instructions.
- ◆ The production and lot release is subject to a controlled QA system.

**Packaging specifications:**

**Fig. 80**

- ◆ The product is filled into PE plastic bottles or aerosol cans (squeeze bottles) approved for cosmetic and pharmaceutical products.
- ◆ Package size: 30 ml plastic bottle
- ◆ Inscription, identification: see label



## Appendix

### 12.2 Instrument Grease 20012

#### 12.2.1 Product description

The product is an inert, fully synthetic lubricant which is thickened with a new type of PTFE\*) micropowder having a high specific surface area.

\*) PTFE

Polytetrafluorethylene is an unbranched, linearly structured, partially crystalline polymer consisting of fluorine and carbon. The colloquial name of this plastic material is often its trade name Teflon.

#### 12.2.2 Field of use

The product is used for maintaining the movability and partially also for sealing as well as to prevent frictional corrosion in the case of metal-to-metal sliding surfaces.

#### 12.2.3 Additional notes and instructions for use



##### **CAUTION!**

*Do not use this product on non-oil-resistant instruments.*

- ◇ Reprocess the instruments before you apply Instrument Grease 20012.
- ◇ Apply Instrument Grease 20012 sparingly on the entire sliding surface to obtain sufficient lubrication.
- ◇ Remove any excess instrument grease with a suitable lint-free and hygienic fibrous materials.



##### **IMPORTANT!**

*Greased components must be sterilized in disassembled condition. The applied grease layer maintains its sliding and sealing function even after sterilization.*

- ◇ Before use, assemble the greased components and check proper functioning.
  - ◆ Follow the product-specific instruction manual.

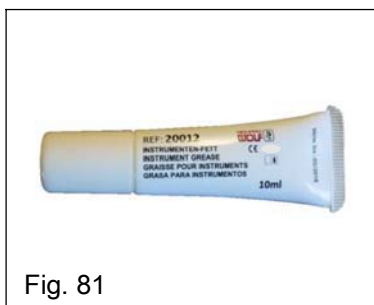


Fig. 81

#### Packaging specifications:

##### Fig. 81

- ◆ The product is offered in a 10ml tube.
- ◆ Inscription, identification: see label

## 13 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)**  
Instrumente werterhaltend aufbereiten  
*[Instrument Reprocessing (Red brochure: 10th edition 2012)  
Reprocessing of Instruments to Preserve Value]*
- ◇ **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 - Prüfmethode  
*[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 Gesundheitsfürsorge  
*[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 years of publishing of the individual parts)  
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]*

- ◇ **UVV BGV A1 und Berufsgenossenschaftliche Regeln**  
z.B. 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 Desinfektionsmittel 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 Desinfektionsmittel- 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, BVMed, [www.bvmd.de](http://www.bvmd.de)**  
*[Returned goods in medical institutions, fact sheet - Treatment Recommendations, BVMed, [www.bvmd.de](http://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
- ◇ **AAMI TIR30: 2011**  
A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices. Association for the Advancement of Medical Instrumentation, 2010, 2011. Arlington, VA
- ◇ **AAMI TIR34: 2007**  
Water for reprocessing of medical devices. Association for the Advancement of Medical Instrumentation, 2010, 2011. Arlington, VA

## Index

### 14 Index

#### B

Booster, 52

#### C

Chemicals for reprocessing, 1  
 Chloride concentrations, 10  
 Chlorides, 10  
 Cleaning accessories, 60  
 Cleaning agents and disinfectants, 13  
 Cleaning and disinfectant solutions in powder form,  
 13  
 Cleaning brushes, 62  
 Clogging, 17  
 Corrosion, 10  
 Creutzfeldt-Jakob Disease, 2

#### D

Deposits, 28  
 Diffusion amplifier, 52  
 Discoloration, 10  
 Discolorations, 51  
 Disinfection efficacy, 12  
 Disposable items, 3  
 Dry preparation at the point of use, 12

#### E

Efficacy, 53  
 Encrustations, 33  
 Enzymatic cleaner, 15  
 Escherichia coli, 10  
 Ethylene oxide (EO), 6, 7, 53

#### F

Flash method, 49  
 Flow method, 49  
 Fractional flow method, 49  
 Fractional pre-vacuum procedure, 48  
 Full demineralization, 10

#### G

Gravity / displacement, 49

#### H

H<sub>2</sub>O<sub>2</sub>, 12, 33  
 Hardness deposits, 10  
 High Level Disinfection, 54  
 Hydrogen peroxide, 53  
 Hydrogen peroxide plasma, 51  
 Hydrogen peroxide solution, 12

#### I

Incubation period, 10  
 Instructions for use, 1  
 Instrument grease, 46, 65  
 Instrument oil, 45, 63  
 Interaction, 51  
 Ion exchanger, 10

#### L

Last rinsing, 13  
 Latest version of the Manual / Instructions for Use, 1  
 Light entry or light exit areas, 30, 31  
 Low temperature steam and formaldehyde, 6, 7  
 Low-temperature sterilization, 51



## M

Manual pre-cleaning, 16  
Manuals, 1  
Material compatibility, 1, 6, 28, 53  
Microbial carry-over, 11, 12

## N

Neutral cleaner, 14  
Neutralizer, 14

## P

Peracetic acid, 13, 54  
Phenols, 13  
Physiological saline , 2  
Pitting corrosion, 10  
Point of use, 11  
Pre-vacuum method, 49  
Product versions, 8  
Proof of efficacy, 1  
Protection cap, 50  
Protective cap, 16, 36  
Protein denaturation, 29  
Pseudomonas, 10

## R

Rental instruments, 2  
Reprocess disposable items, 3  
Residues, 11, 17  
RIWO SYSTEM TRAY, 27, 54

## S

Sequence of reprocessing steps, 5  
Silicic acid (silica), 10  
Silicone peg mats, 27  
Small parts sieve, 30  
Spray contamination, 29  
Spray oil, 45  
Sterile water treatment, 59, 61  
Sterilization validations, 51  
STERIS SYSTEM, 6, 7  
STERIS SYSTEM 1, 54  
STERIS SYSTEM 1E, 54  
STERRAD, 6, 7  
STERRAD 50 / 100S / 200 / NX and 100 NX, 51  
Storage, 56  
Storage systems, 54

## T

Thermal procedure, 14  
Total bacteria count, 10  
Transport , 12  
Transport and storage systems, 12

## U

Ultrasonic bath, 37

## V

Validation, 5

## W

Water ingredients, 10  
Water quality, 10  
WD devices, 13  
Wet preparation at the point of use, 12

