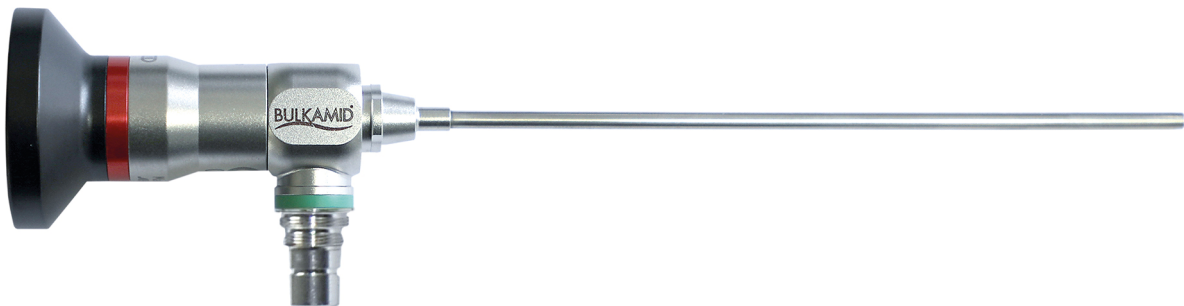


Axonics

BULKAMID[®]

Instructions For Use Cystoscope (not valid for USA)



IMPORTANT! Save this document to a local drive or file a printed copy in case of network issues.

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0 Important Information about this Document

0.1 Scope of Validity, Identification, Purpose

These instructions for use apply to the following products:

41-0152a, 41-0152a-FX

The intended users are physicians, medical assistants, and employees of central sterile supply.

These instructions for use do not describe endoscopic procedures or techniques during surgery.

0.2 Using and Storing this Document

These instructions for use must be stored in a defined location so that they may be accessed at all times by the intended users.

In the event of the sale of this device or its relocation, this document must be handed over to the new owner.

1 General Safety Information

1.1 Safety Messages in this Document

The severity of a hazard is indicated by the following signal words which start each safety message.

WARNING - hazard that can result in **death or serious injury**.

CAUTION - hazard that can result in **minor or moderate injury**.

ATTENTION - hazard that can result in **material damage**.

Take time to read safety messages carefully and bear them in mind when performing the affected activities.

1.1.1 Safety Messages at the Start of a Chapter

The safety messages described in the following can be found accumulated at the start of chapters. They describe dangers which persist during the entire task.

Safety messages at the start of a chapter are built as follows:



⚠ WARNING


Nature and origin of the risk.
Consequences of the danger.

▶ Measures to prevent danger.

1.1.2 Safety Messages in the Body of the Text

The following safety messages will be listed within the body of the instructions directly prior to any steps that carry a particular risk.

Safety messages in the body of the text are built as follows:

 **CAUTION!** Nature and origin of the risk. Consequences of the danger.

▶ Measures to prevent danger.

1.2 Product Safety

1.2.1 Basic Safety Notices

Hazards may occur during all phases of the product life cycle.

The device must be operated only in a fault-free condition in accordance with the intended use and the instructions for use. Before each use, check that the device and accessories to be used are free of damage and in full working order.

The original packaging should be retained and reused when returning the device for servicing.

Follow the instructions for use for all devices and instruments that are to be used in conjunction with this device.

1.2.2 Hazard Sources

Nature and origin of the risk	Explanation	Preventive action
Risk of injury due to unauthorized modifications of the product	Unauthorized modifications influence product safety	Do not make any unauthorized modifications to the product.
Risk to the patient due to component failure	Components may fail during a surgical procedure	Keep spares on hand for emergency replacement.
Risk to the patient resulting from damaged device	The product may be damaged by improper handling	Handle the product with care. Do not continue to use the product after heavy mechanical stress or falls.

Nature and origin of the risk	Explanation	Preventive action
		Send product in for inspection after any heavy mechanical stress or fall.
Risk to the patient due to improper use	Risk to the patient, user and other persons, or premature wear of the device	Only use product according to intended use. Always follow instructions for use.
Risk of suffocation by packaging material	Children can suffocate on packaging materials	Keep packaging material out of reach of children.
Risk of injury by electromagnetic interactions	During magnetic resonance imaging (MRI) electromagnetic interactions occur. This may cause heating of metal components.	Do not operate the device in the vicinity of MRI scanners.
Risk of injury due to wrong ambient conditions	At wrong ambient conditions irreversible tissue damage or unwanted coagulation, injuries of the operator as well as damages to property are possible	Observe operating conditions as well as transport and storage conditions.
Risk of infection by unsterile delivery	Product and accessories are shipped unsterile	Carry out reprocessing of the device and its accessories prior to first use.
Injury to eyes due to high-intensity light	The light provided by the light source has a high radiant power which may lead to injuries to the eyes	Do not look directly into the open end of the light guide or light exit of the endoscope. Set light source to lowest possible amount of light or use automatic light control.
Risk of injury by electric shock	Possible electric shock during application of a defibrillator	Before discharging a defibrillator, remove the product from the surgical field.
Risk of injury by electric shock	When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive.	This is particularly important for type CF applied part endoscopes, in which case a type CF applied part energized endotherapy device should be used in order to minimize total patient leakage current.
Reactions to used materials	The product may consist of metal alloys containing cobalt.	Note the symbol on the packaging label.
Damages to the product due to improper handling	The product contains sensitive optical components	Don't bend or bump the product. Put down the product with care. Avoid lever forces and scratches to the surface. Take care when removing instruments from the surgical field.

1.2.3 Staff Qualifications

The qualifications required for the personnel are stated in the respective chapters of this document and must be observed.

2 General Information about the Device

2.1 Scope of Delivery

The scope of delivery for the device includes:

- 1x endoscope, comprising (pre-installed on the endoscope):
 - endoscope light guide adapter, Wolf systems
 - endoscope light guide adapter, Storz systems
- 1x instructions for use
- 1x protective tube (only for shipping)

Check the delivery for damage and for completeness.

2.2 Product Description

2.2.1 Performance Characteristics and Function

Cystoscopes are rigid endoscopes for visualizing the urethra and the urinary bladder during the performance of endoscopic procedures in urology.

Rigid endoscopes consist of a fiber optic cable and sensitive image transmission system with eyepiece.

The fiber optic cable is used to illuminate the site inside the body. The connector for connecting the light guide to the light source is situated at the proximal end of the endoscope. The required endoscope light guide adapters are included in the scope of delivery.

The distal end of the endoscope features an objective lens that captures the image from inside the body. The image is sent through the image transmission system to the eyepiece.

The eyepiece cap connects the eyepiece to an endocoupler that transmits the image to a camera.

Note: During this medical application, adhere to national statutory regulations and directives.

2.2.2 Visual Overview

Cystoscope

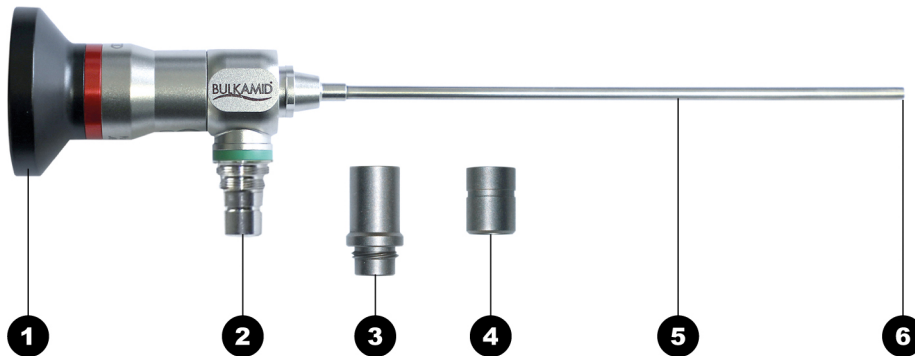


Figure 2-1: Cystoscope.

- 1 Eyepiece cap
- 2 Light guide connector (ACMI)
- 3 Endoscope light guide adapter, Storz systems
- 4 Endoscope light guide adapter, Wolf systems
- 5 Endoscope sheath
- 6 Endoscope tip

2.2.3 Required Accessories

There is no guarantee that instruments selected solely using maximum insertion portion width and working length will be compatible in combination.

Compatible sheaths and working elements are required for cystoscopic procedures. Use sheaths and working elements that are compatible with the cystoscopes as per the manufacturer's specifications in the instructions for use. For this purpose, the technical data given in [section](#) regarding system compatibility, working length, outer diameter of insertion portion and direction of view must be observed.

2.3 Usage

2.3.1 Intended Use

The cystoscopes are used when performing endoscopic, diagnostic and therapeutic surgical procedures.

Examples of the use of the devices include visualization and tissue manipulation as long as this is considered appropriate by the surgeon.

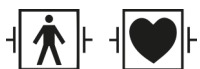
The cystoscopes are intended to be used in urological surgery. A natural body orifice is used for minimally-invasive access.

The products are intended to be used in combination with medical electrical devices that meet **at minimum** the type **BF** classification requirements according to IEC 60601-1 for elevated protection from electric shock.

This insulation barrier can be realized by the medical electrical devices themselves or by the connection cables to the endoscope and must be assured for every connection between the endoscope and connected devices.



Devices or connection cables that meet the type BF or the higher type CF classification requirements for applied parts feature one of the adjacent symbols.



Defibrillation-proof devices or connection cables are also compatible. These will be marked with one of the adjacent symbols depending on the degree of protection against electric shock offered.

2.3.2 Indications

The indications for an endoscopic application depend on the medical condition of the patient and the individual risk/benefit analysis by the surgeon.

During this medical application, adhere to national statutory regulations and directives.

2.3.3 Contraindications

Contraindications may exist depending on the patient's general condition or specific symptoms.

The decision to perform a procedure remains with the responsible surgeon and must be made on the basis of an individual risk/benefit analysis.

Cystoscopy may be contraindicated by the following clinical conditions, depending on their severity or extent:

- Acute urethritis
- Acute cystitis
- New urethral trauma
- Acute pelvic inflammatory disease

2.4 Marking

Observe the symbols used on product and packaging.

In addition to the international standardized symbols, we use the following symbols:



The device is suitable for autoclave sterilization



Fully refurbished device ("refurbished device")



Federal (US) law restricts this device to sale by or on order of a physician

Find a list of all symbols used on the product, packaging and in documents online:

<https://ifu.schoelly.de>



2.5 Service Department Contact Details

If you have any questions about our products, their installation, or use, or you wish to arrange servicing, please contact one of our subsidiaries.

You will find contact details on the back of this document.

2.6 Obligation to Report Serious Incidents

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

3 Operation

3.1 Safety Notices



WARNING

Interactions between devices in simultaneous use (e.g. lasers, electrosurgery)

Risk to the patient and user, image interference, damage to the device

- > Ensure that all the devices in use meet at minimum the requirements classified as type BF according to IEC 60601-1
- > Observe the labeling and instructions for use of the devices used
- > Avoid direct contact between the endoscope and conductive parts with active RF electrodes

⚠ WARNING



Use of non-sterile parts and recontamination

Infection risk for the patient

- > Use only properly reprocessed endoscopes and endoscopic accessories
- > Accessories supplied in a non-sterile condition must be subject to reprocessing before use
- > Always carry out a visual inspection prior to use
- > Anchor the light guide in the surgical field and secure against slipping, allowing some slack for maneuvering
- > Adhere to the infection control practices that are in place

⚠ WARNING



Contact of bladder cancer patients with Cidex® OPA

Possible anaphylactic reaction

- > Do not bring patients with a history of bladder cancer in contact with devices that were disinfected using Cidex® OPA
- > Use automated cleaning and thermal disinfection, if applicable

⚠ CAUTION



High temperatures resulting from light source usage*

Irreversible tissue damage to patient or undesirable coagulation, user injury, material damage

- > Use only light guides that are suitable for use with the endoscope
- > Always use a sheath with endoscope
- > You should always use the lowest possible light output setting that will allow you to illuminate the target area and use intense light as short as possible
- > Do not touch light guide connections
- > Do not allow the distal end of the endoscope to come into contact with patient tissue or with combustible or heat-sensitive materials
- > Do not exceed the maximum permitted ambient conditions for the endoscope
- > When there is potential for the shaft of the endoscope to come in direct contact with body tissues (e.g. confined anatomical space), do not maintain the same position for extended periods of time (> 10 minutes)

* Applied part as per IEC 60601-1 can reach temperatures of > 41 °C (106 °F) up to 48 °C (118 °F).

⚠ CAUTION



Coupling laser beams into the endoscope

Damage to the eyes caused by looking directly into the eyepiece

- > Wear laser safety glasses

3.2 Staff Qualifications

The device may be operated only by physicians and medical assistants who have received instruction in how to use the device and who have the requisite training or advanced training, knowledge, and practical experience in the endoscopic procedure to be applied as defined by the provisions in place at the site of operation.

3.3 Technical Inspection Prior to Use

3.3.1 Performing a Visual Inspection

A visual inspection must be performed **prior to each use**.

Inspect	Exclusion Criteria
Endoscope and components are undamaged	sharp edges or corners, bulges, or rough surfaces that might cause injury to the patient
Fiber optics are in working order	more than 20 % of the fibers remain dark

Inspect	Exclusion Criteria
To do this, hold the distal end toward a bright light (not a cold light source) and the light guide connection toward your eyes. Gently move the endoscope from side to side, taking note of the brightness of the fibers.	
glass surfaces and fiber optic end faces of the endoscope are clean and smooth	soiled or scratched surfaces
clear, bright, complete image is visible Look through the eyepiece and assess the image quality.	image is yellowed, dark, speckled, or cropped
equipment to be used for the procedure is mutually compatible and can be inter-locked, if applicable	Incompatible equipment, locking mechanism is not working

Table 3-1: Visual inspection

3.3.2 Performing a Function Check

A function check must be performed **prior to each medical procedure**.

1. Connect a camera.
2. Check that camera head and endoscope are firmly seated and securely connected to each other.
3. Switch on all the system components that you intend using for the procedure.
4. Direct the camera head at a nearby object in the room and focus the image.

Check that you are able to achieve a sharp, bright, good quality image in correct orientation.

Do not use the system if the image contains vertical lines or color variations, flickers, or you are unable to achieve a sharp, bright, good quality image or the image orientation is not correct.

3.4 Connecting a Light Guide

The specifications for compatible light guides are:

- Fiber bundles of 3.5 mm Ø
- Length up to 3000 mm

Different light guides require different light guide adapters to connect to the endoscope.

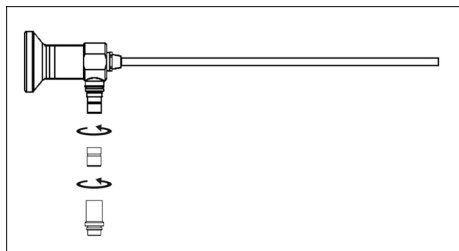


Figure 3-1: Mounting endoscope light guide adapters.

1. Screw the suitable light guide adapter to the light guide connector on the endoscope and, if applicable, to the light guide.
2. Connect the light guide to the light guide connector.

3.5 Stopping Usage and completing Pre-Cleaning

Complete the pre-cleaning process **immediately after use**.

1. Remove and discard the sterile drape, if present.
2. Uncouple the endoscope from the endocoupler.
3. Detach the light guide and all detachable parts (such as light guide adapters).

NOTICE! The eyepiece cap is non-detachable.

4. Pre-clean the product by wiping it with a lint-free and wetted, but not dripping wipe until no more residue can be seen.
5. Dry the product using a soft, lint-free wipe.

Ensure that the product is reprocessed within **6 hours**.

4 Reprocessing

4.1 Safety Notices



⚠ WARNING

If the product is potentially contaminated with Creutzfeldt-Jakob pathogens, it is not suitable for reprocessing

Risk of cross-contamination during use and reprocessing

- > Do not reprocess products that are potentially contaminated, but dispose of immediately.



⚠ CAUTION

Improper cleaning and disinfection

Risk to patient as a result of inadequate cleaning and disinfection, damage to the device

- > Use an automatic washer/disinfector that meets the performance requirements of ISO 15883-1
- > Reprocess all detachable parts (such as light guide adapters, see [section 2.2.2](#)).
- > Load the device with care: all contents must be rinsed and cleaned fully (no rinsing 'blind spots')
- > Connect instruments with lumens and channels directly to the dedicated ports on the reprocessing tray
- > Disassemble all valves on instruments
- > Ensure that the washer/disinfector is properly maintained
- > Only use cleaning and disinfecting agents that are approved for the product
- > When pre-cleaning, do not use temperatures in excess of 45 °C that could fix soiling on the product
- > When pre-cleaning, do not use fixing cleaning and disinfecting agents (active ingredients: Aldehyde, alcohol) that could fix soiling on the product

NOTICE

Contact with chloride-based solutions

Corrosion and destruction of the device

- > Avoid contact with chloride-based solutions, which can be found, for example, in surgical residue, lotions, drugs, saline solutions, and cleaning and disinfecting agents
- > After contact with chloride-based solutions, rinse products sufficiently with deionized water and dry completely

NOTICE

Use of ultrasonic bath

Damage to the endoscope

- > Do not expose endoscope to ultrasonic bath

NOTICE

Unsuitable cleaning agents and process chemicals

Corrosion damage, premature aging, and visible material changes

- > Only use cleaning and disinfecting agents that are approved for the product
- > Only use process chemicals that are compatible with the device's materials according to the chemical manufacturer's recommendations
- > Follow all the chemical manufacturer's application specifications regarding temperature, concentration, and contact time
- > Do not use process chemicals that can cause stress cracking or brittleness of plastic materials

Devices were investigated for device functionality after 500 reprocessing cycles. Devices may still be functional afterwards if they pass the prior-to-use inspection ([section 3.3](#)).

4.2 Staff Qualifications

The reprocessing of medical devices must always fall under the responsibility of qualified personnel who have the necessary knowledge and expertise.

This knowledge and expertise can be acquired by completing further training in this field or as a result of completing a dedicated qualification with practical experience, supplemented by appropriate further training measures, where required.

4.3 Validated Procedures

The reprocessing procedures specified in this document were validated for efficacy.

It is the operator's responsibility to introduce, document, apply, and maintain a validated reprocessing procedure.

Make sure that the equipment used for reprocessing is properly maintained.

4.4 The Process Flow

The product has to be prepared for reprocessing immediately after use by pre-cleaning. See [section 3.5](#).

The reprocessing procedure described in this document consists of the following steps:

- Pre-cleaning immediately after use
- Cleaning and disinfection (manual or automated)
- Sterilization

During reprocessing, staff should wear personal protective clothing.

The product must be cleaned thoroughly at the beginning of reprocessing. It is essential that the sterilization medium reaches all parts of the product.

The optimum and most reliable reprocessing results are achieved using automated cleaning and disinfection with subsequent steam sterilization using the pre-vacuum steam procedure.

Adhere to national statutory regulations, national and international standards and directives, and the infection control practices that are in place at your institution for reprocessing.

New and returned products following repair have to undergo complete reprocessing before first use.

The alternating use of different reprocessing methods can cause premature aging of the product.

Excessive doses of neutralizers and cleaning agents can damage the product and cause laser engravings to fade.

Please see www.a-k-i.org for more detailed information about hygienically safe, value-preserving reprocessing methods that also protect the materials.

4.5 Cleaning and Disinfecting Agents and Auxiliary Materials

The **manual cleaning process** was validated using:

- Cidezyme®/Enzo® (Johnson & Johnson)

The **manual disinfection process** was validated using:

- Cidex® OPA (ASP)

The **automated cleaning process** was validated using:

- neodisher® MediClean forte 0.5 %
(Chemische Fabrik Dr. Weigert GmbH & Co. KG)

Wherever possible, use the above cleaning and disinfecting agents only.

Before use, read the manufacturer's user information carefully and follow the specifications regarding concentration, temperature, usage time, water quantities, and contact time.

Auxiliary materials

Use the following auxiliary materials:

- **Wipes:** soft, clean, lint-free
- **Brush:** soft bristled

4.6 Manual Cleaning and Disinfection

4.6.1 Overview

Stage	Work step	Temperature (°C/°F)	Time (min)	Water quality	Cleaning/ disinfectant solution
I	Cleaning	as per manufacturer's instructions	2-5	Drinking water	Enzymatic cleaning solution
II	Rinsing 2x	< 45/113	2x ≥ 1	Drinking water	---
III	Disinfection	as per manufacturer's instructions	12	---	Disinfectant solution (undiluted)
IV	Rinsing 2x	< 45/113	2x ≥ 1	Drinking water	---
V	Final rinsing	< 45/113	≥ 1	Deionized water*	---
VI	Drying	---	---	---	---

Table 4-1: Overview of manual cleaning and disinfection.

* Deionized water = demineralized, low-germ, max. 10 germs/ml, as well as low in endotoxins, max. 0.25 endotoxin units/ml

4.6.2 Performing Manual Cleaning and Disinfection

Complete stage I: Cleaning

NOTICE! Scratch-sensitive surface. Risk of abrasion. Do not use metal brushes, metal objects, or abrasive cleaners. To remove soiling on optical surfaces, use pads soaked with cleaning solution only.

Note: Use fresh water for each rinse and allow residual water to drip off for a sufficient length of time.

1. Completely immerse all parts used of the fully disassembled product in the cleaning solution for **2 to 5 min**.

Make sure that all accessible surfaces remain immersed in the cleaning solution throughout the entire cleaning time.

2. While the components soak in the solution, use a soft wipe or soft brush to remove all visible residue from all exterior surfaces of the components.
3. Then clean the product soaking in the cleaning solution for a minimum of **1 min** using a soft, lint-free wipe or a soft-bristled brush.

Complete stage II: Rinsing

1. Completely immerse all parts in drinking water (< 45 °C / 113 °F) and thoroughly rinse all accessible surfaces in **2 rinses** of at least **1 min** each.

Complete stage III: Disinfection

1. Completely immerse all parts in disinfectant solution for at least **12 min**.
2. Remove all adherent air bubbles from the component surfaces.

All accessible surfaces must remain immersed in the disinfectant solution bath throughout the entire disinfecting time.

Complete stage IV: Rinsing

1. Completely immerse the product in drinking water (< 45 °C / 113 °F) and thoroughly rinse all accessible surfaces in **2 rinses** of at least **1 min** each.

Complete stage V: Final rinsing

1. Completely immerse all parts in deionized water (< 45 °C / 113 °F) and thoroughly rinse all accessible surfaces for a minimum of **1 minute**.

Complete stage VI: Drying

1. Dry all parts with a clean, soft, lint-free wipe/operating room towel or using medical-quality filtered compressed air (pmax = 0.5 bar).
2. After drying, visually inspect the product (see [section 3.3.1](#)) in a well-lit area and make sure it is dry, undamaged and free of visible residue.

Use a magnifying glass. Repeat the cleaning and disinfection process if necessary.

Immediately set aside any damaged products.

4.7 Automated Cleaning and Thermal Disinfection

4.7.1 Overview

Stage	Step	Temperature (°C/°F)	Time (min)	Cleaning solution / water quality
I	Pre-rinsing	Cold	2	Drinking water
II	Cleaning	60/140	10	Alkaline cleaning solution
III	Intermediate rinsing	per the equipment manufacturer's standard cycle	1	Drinking water
IV	Intermediate rinsing	per the equipment manufacturer's standard cycle	1	Drinking water
V	Thermal disinfection	90/194	5	Deionized or purified water A ₀ value: > 3000
VI	Drying	99/210	30	---

Table 4-2: Overview of automated cleaning and thermal disinfection.

Note: Automated reprocessing can cause color-anodized or plastic components (e.g. serial rings and the eyepiece cap) to fade.

4.7.2 Performing Automated Cleaning and Thermal Disinfection

Use a legally marketed washer/disinfector that has been validated as effective. The device must meet the performance requirements of ISO 15883-1 (or the respective country-specific version thereof).

The manufacturer recommends dry removal of the products prior to automated cleaning.

In the case of wet removal, do not use foaming detergents and rinse the products thoroughly prior to the automated cleaning.

Use only legally marketed reprocessing trays that are approved for automated cleaning and thermal disinfection. Observe the instructions for use of the tray.

1. Place all parts in the reprocessing tray.
2. Seal the tray.
3. Place the tray into the washer/disinfector.

Apply a validated loading plan when doing so.

When loading, take care to avoid creating rinsing blind spots.

4. Start the cleaning/disinfection cycle in accordance with the manufacturer's instructions and instructions for use for the device.
5. Remove the reprocessed product from the washer/disinfector.
6. After drying, visually inspect the product in a well-lit area. Products should be dry, undamaged and free of visible residue.

Use a magnifying glass.

Repeat the cleaning and disinfection process if necessary.

Immediately set aside any damaged products.

4.8 Sterilization

4.8.1 Performing Steam Sterilization

Use fully desalinated drinking water that meets the requirements of European Standard EN 285.

Use only legally marketed reprocessing trays that are approved for steam sterilization in an autoclave. Observe the instructions for use of the tray.

1. Make sure that manual or automated cleaning and disinfection is complete and the product has been properly cleaned and dried.
2. Place all parts in the reprocessing tray.
3. Seal the tray.
4. Double-wrap the tray with two single layers of legally marketed sterilization wrap.
5. Load the wrapped tray in the sterilizer as per a validated loading plan. Observe the instructions of the sterilizer manufacturer when doing so.
6. Start the steam sterilization with an autoclave in accordance with the device manufacturer's instructions, using the following parameters:

Cycle type	Pre-vacuum process
Pulses	4
Temperature	134 °C (273 °F)
Holding time	at least 3 min (effective sterilization time)

NOTICE! Products can be shock sensitive when hot. Avoid knocking or shaking.

NOTICE! Damage resulting from a sudden change in temperature. Allow products to cool to room temperature; do not use additional cooling measures.

7. Remove the reprocessed product from the sterilizer.

Ensure that products remain sterile after reprocessing.

5 Maintenance and Repairs

5.1 Troubleshooting

Issue	Possible causes	Fixes
Bad image quality, e.g. Image cloudy, yellowed, too dark or too little illumination	Glass surfaces soiled	Manual cleaning as per chapter 4 , then reprocess, check the water quality
	Leaky, defective lens system	Send the endoscope in for repair
	Unsuitable light guide	Use a suitable light guide
	Light guide incorrectly attached to endoscope	Check that the light guide is seated properly
	Soiled fiber optics	Manual cleaning as per chapter 4 , then reprocess, check the water quality
	Light guide or light source soiled or defective	Check light guide and light source (e.g. by illuminating a white surface)
	Defective fiber optics	Check fiber optics as per section 3.3
Corrosion, staining, discoloration	Inadequate cleaning (e.g. remaining protein residue)	Manual cleaning as per chapter 4 , if necessary, rub thoroughly, then reprocess
	Insufficient rinsing between the reprocessing stages, especially prior to sterilization	Rinse sufficiently between the reprocessing stages
	Excessive concentration of minerals (e.g. Limescale), silicates, (heavy) metals or organic substances	Check the water quality, only use demineralized water if necessary
	Contaminated, too frequently reused cleaning and disinfecting solution	The cleaning and disinfecting solution should be replaced regularly
	Extraneous rust, e.g. resulting from rust contained in steam or damaged or non-corrosion-resistant instruments reprocessed at the same time	Check the supply systems, if multiple items are being reprocessed together, pay attention to material compatibility and signs of prior damage; prevent the different items from touching one another
	Contact corrosion	Avoid contact with other devices

Table 5-1: Troubleshooting table.

5.2 Repair

Should you need to arrange a repair for the device, please contact our Service Department.

When you return the device, please also enclose a detailed **description of the fault**.



WARNING

Contaminated device

Risk of infection

> Reprocess the product prior to shipping (*chapter 4*)

The device should be returned in its original packaging, if possible.

Affix a label to the outer packaging indicating the reprocessing status.

We reserve the right to refuse acceptance of unlabeled packages and to return them to sender.

6 Product Data

6.1 Technical Data

Item no.	DoV	FoV	WL (mm)	Ø (mm)
41-0152a / 41-0152a-FX	0°	Standard	113	2.7

Table 6-1: Technical Data

Item no. = Item number

DoV = Direction of view

FoV = Field of view

WL = Working length

Ø = Outer diameter of insertion portion

Factory Exchange [FX] (factory exchange)

Cystoscope 2.7 mm x 113 mm, 0° (41-0152a-FX)

Devices with an item number ending in „FX“ have been repaired or refurbished to meet original product specifications.

6.2 Ambient Conditions

Transport and storage conditions

Temperature	-20 °C to +70 °C
Relative air humidity	5 % to 95 %
Atmospheric pressure	70 kPa to 106 kPa

Reprocessed devices must be protected against recontamination, in a dark, dry, well-ventilated, dust-free and light-controlled location with a consistent temperature.

Direct sunlight, high temperatures, high humidity or radiation can damage the device or present a risk of infection.

When placing into storage, make sure that the device cannot be damaged by other instruments. It is therefore best to store the device individually or use containers in which it can be secured.

Operating conditions

Temperature	+15 °C to +40 °C
Relative air humidity	10 % to 95 %
Atmospheric pressure	70 kPa to 106 kPa



CAUTION

Non-observance of the ambient conditions

Irreversible tissue damage to patient or undesirable coagulation, user injury, material damage

> Observe operating conditions as well as transport and storage conditions

6.3 Spare Parts and Accessories

Use original spare parts and accessories only.

Image	Designation	Item number
	Endoscope light guide adapter, Storz systems	05.0114z


Image	Designation	Item number
	Endoscope light guide adapter, Wolf systems	05.0116b

Table 6-2: Spare parts and accessories.

7 Disposal



WARNING

Contaminated device

Risk of infection

> Reprocess the product prior to disposal ([chapter 4](#))

When disposing of or recycling the device and its components, you must adhere to the applicable national regulations governing waste disposal and recycling.

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