Instructions For Use

Laparoscopes
Endoscopes for Laparoscopy
(USA)

Table of Contents

0 Important Information about this Document

0.1 Scope of Validity, Identification, Purpose

These instructions for use apply to the following products:

Item numbers

11.0031a

11.0041a

11.0043a

11.0055a

11.0057a

11-0231a

11-0243a

11-0131nir

11-0143nir

These instructions for use are an integral component of the product and contain all the information required by users and operators for safe and proper use.

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

0.2 Target Group

These instructions for use are intended for physicians, medical assistants, and employees of central sterile supply who are entrusted with the operation, handling, and reprocessing of the device.

0.3 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 target group.

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

1 General Information about the Device

1.1 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

Check the delivery against the delivery note for completeness and damage.

The delivery left our premises in perfect condition. If you have any cause for complaint, however, please contact our Service Department.

1.2 Product Description

1.2.1 Performance Characteristics and Function

Rigid endoscopes permit the visualization of the inside of the body and body cavities. Depending on its design, an endoscope can also perform additional tasks.

Depending on the endoscopic discipline and anatomical region, the approach to the body cavity may be through a natural orifice or a surgically created opening.

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 endoscope light guide adapters required to connect light guides 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, which transmits the image to a camera. The camera's controller converts the signal so that the image can be displayed on a monitor.

Endoscopes labeled as NIR-sensitive are sensitive in the visible and near-infrared (NIR) spectrum. In combination with a specialized imaging system, the endoscopes can be used for NIR fluorescence imaging.

Special instruments are required for endoscopic procedures; these may vary depending on the endoscopic discipline concerned.

It is the surgeon's responsibility to make sure the instruments required for a particular endoscopic procedure are assembled and available for use.

1.2.2 Visual Overview

A laparoscope design illustration is provided below.

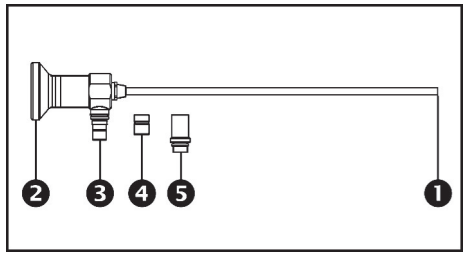


Figure 1-1: Laparoscope illustration.

1. Objective
2. Eyepiece
3. Light guide connector (ACMI)
4. Endoscope light guide adapter, Wolf systems
5. Endoscope light guide adapter, Storz systems

1.2.3 Required Accessories

Additional instruments are required for endoscopic procedures. It is the surgeon's responsibility to make sure the instruments required are assembled and available for use.

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

Depending on the laparoscope used (*section 6.1*) standard trocars with a diameter suitable for 5 mm or 10 mm endoscopes are required for the application.

1.2.4 Compatible Light Guides

The specifications for light guides compatible with laparoscopes of 5 mm working diameter are:

- Fiber bundles of 3.5 mm Ø
- Length up to 300 cm

The specifications for light guides compatible with laparoscopes of 10 mm working diameter are:

- Fiber bundles of 3.5 to 4.8 mm Ø
- Length up to 300 cm

Laparoscope technical data see *section 6.1*.

The endoscope light guide adapters included in the scope of delivery (*section 1.1*) allow for the connection of light guides from different manufacturers.

1.3 Usage

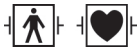
1.3.1 Intended Use

The devices are intended to be used in combination with medical electrical devices that are, as a **minimum**, compliant with the requirements for applied parts classified as type **BF** (that is parts offering increased protection against electric shock), according to IEC 60601-1.

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 classification requirements for applied parts feature the adjacent symbol.

Type CF is the most stringent classification for devices and connecting cables considered applied parts within the meaning of IEC 60601-1. Devices bearing the CF symbol (the adjacent heart symbol) are approved for direct conductive contact with the heart.



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.

1.3.2 Indications for Use

The laparoscopes described in these instructions for use are indicated for examination of body cavities, hollow organs, and canals, and using additional accessories, to perform various diagnostic and therapeutic procedures.

1.3.3 Contraindications

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

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

1.4 Conformity

1.4.1 Standards and Directives

The device meets the requirements of the following applicable standard:

- **IEC 60601-2-18** Medical electrical equipment - Part 2-18:
  Particular requirements for basic safety and essential performance of endoscopic equipment

1.4.2 Medical Device Classification

The product is a Class IIa medical device within the meaning of applicable **EU guidelines**.

1.5 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

NIR sensitive

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

1.6 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.

1.7 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.

2 General Safety Information

2.1 Safety Messages in this Document

2.1.1 Safety Messages at the Start of a Chapter

The safety messages described in this section will be listed at the start of any chapter containing instructions that carry a particular risk.

The severity of the potential risk is expressed by the signal word in the beginning of the message.

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

The following kind of message refers to a risk that could lead to death or serious injury:

⚠ WARNING

Nature and origin of the injury risk

Potential consequences of non-observance

> Preventive action

The following kind of message refers to a risk that could lead to minor or moderate injury:

⚠ CAUTION

Nature and origin of the injury risk

Potential consequences of non-observance

> Preventive action

The following kind of message refers to a risk that could lead to material damage:

NOTICE

Nature and origin of the risk of material damage

Potential consequences of non-observance

> Preventive action

2.1.2 Safety Messages in the Body of the Text

The warnings described in this section will be listed within the body of the instructions directly prior to any steps that carry a particular risk.

The severity of the potential risk is expressed by the signal word in the beginning of the message.

Read through these safety messages carefully and take the preventive action indicated.

The following kind of message refers to a risk that could lead to death or serious injury:

⚠ **WARNING!** Nature and origin of the risk. Potential consequences of non-observance. Preventive action.

The following kind of message refers to a risk that could lead to minor or moderate injury:

⚠ **CAUTION!** Nature and origin of the risk. Potential consequences of non-observance. Preventive action.

The following kind of message refers to a risk that could lead to material damage:

NOTICE! Nature and origin of the risk. Potential consequences of non-observance. Preventive action.

2.2 Product Safety

2.2.1 Basic Safety Notices

Our products are developed and manufactured to the highest quality standards.

Although this product corresponds to the current state of the art, risks could still arise during initial operation, use, reprocessing or maintenance.

Therefore, it is important that you read through these instructions for use carefully. Observe the warnings indicated.

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.

⚠ **WARNING!** This device is supplied in a non-sterile condition. Risk of infection. Carry out reprocessing of the device and its accessories prior to first use.

⚠ **WARNING!** Unauthorized modifications to the device. Risk of serious injury to persons. Do not make any unauthorized modifications.

⚠ **WARNING!** Component failure during a surgical procedure. Risk to the patient. Keep spares on hand for emergency replacement.

⚠ **WARNING!** High-intensity light source. Risk of injury to eyes. Do not look directly into the open end of the light guide or light exit of the endoscope.

⚠ **WARNING!** Magnetic resonance imaging (MRI). Magnetic force, electromagnetic interactions, heating of metal components. Do not operate the device in the vicinity of MRI scanners.

⚠ **WARNING!** Using the device during operation of a defibrillator. Risk to persons. Before discharging a defibrillator, remove device from the surgical field.

⚠ **CAUTION!** Rough handling. Risk to the patient resulting from damaged device. Handle the product with care. If the device is dropped or subjected to high mechanical stress, stop using it and send it in to the manufacturer for inspection.

⚠ **WARNING!** Improper handling, maintenance, and use carries a risk to the patient and user, or can lead to premature wearing of the device.

⚠ **WARNING!** When energized endoscopes are used with energized endotherapy devices, patient leakage currents may be additive. This is particularly important if a type CF applied part endoscope is used, in which case a type CF applied part energized endotherapy device should be used in order to minimize total patient leakage current.

⚠ **CAUTION!** Incompatible combination of system components when used for NIR fluorescence imaging. Degradation of performance, function and image quality. Observe the complete system requirements and warnings in the instructions for use supplied with the specialized imaging system.

Note: The product may consist of metal alloys containing cobalt. Refer to the corresponding pictogram on the packaging label.

2.2.2 Staff Qualifications

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

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 HF electrodes
- > Do not activate HF electrodes in the vicinity of flammable gases or liquids
- > Before using HF devices, ensure that all potentially explosive gas mixtures and liquids have been extracted

⚠ WARNING

Displaying a recorded image instead of the live image or an altered image orientation

Risk to the patient

- > Ensure that the monitor is displaying the live image from the endoscopic camera
- > Ensure that the live image is displayed in the correct orientation (not mirrored)

⚠ WARNING

Use of non-sterile parts

Infection risk for the patient

- > Use only properly reprocessed endoscopes and endoscopic accessories
- > 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

⚠ WARNING

Recontamination resulting from improper handling

Infection risk for the patient

- > Adhere to the infection control practices that are in place

⚠ 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
- > Avoid the prolonged use of intense light
- > Only use the laparoscope with a compatible trocar
- > You should always use the lowest possible light output setting that will allow you to illuminate the target area
- > Do not touch the light source in the vicinity of the lamp
- > 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 operating conditions for the endoscope

* Applied part as per IEC 60601-1 can reach temperatures of > 41 °C (106 °F) up to 43 °C (109 °F).

⚠ CAUTION

Coupling laser beams in the endoscope

Damage to the eyes caused by looking directly into the eyepiece

- > Wear laser safety glasses

NOTICE

Improper handling

Risk of damage to the product

- > Set down carefully without bending or knocking
- > Avoid lever forces
- > Avoid scratching the surface
- > Take care when removing instruments from the surgical field

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**.*

1. Check the endoscope and all the components to be used for external damage.

   Do not use the product if it has any sharp edges or corners, bulges, or rough surfaces that might cause injury to the patient.

2. Check that the fiber optics in the endoscope are in full working order.

   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.

   If more than 20 % of the fibers remain dark, the device must not be used. Submit the endoscope to repair.

3. Check that the glass surfaces and fiber optic end faces of the endoscope are clean and smooth.

   Do not use the endoscope if the surfaces are soiled or scratched. Set aside the endoscope and follow the steps described in *section 5.1*.

4. Make sure you can see a clear, bright, complete image.

   Look through the eyepiece and assess the image quality.

   Do not use the endoscope if the image is yellowed, dark, speckled, or cropped. Set aside the endoscope and follow the steps described in *section 5.1*.

5. Check that all the equipment to be used for the procedure is mutually compatible and can be interlocked, if applicable.

   Only use the OR equipment if the isolation barrier for protecting against electric shock meets **at minimum** the type **BF** classification requirements according to IEC 60601-1 (see *section 1.3.1*).

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.

   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.

3.4 Connecting a Light Guide

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

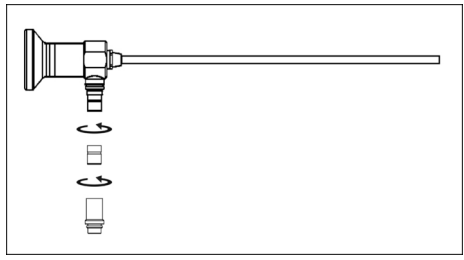


Figure 3-1: Mounting endoscope light guide adapters.

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 at the conclusion of the surgery 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.
6. Arrange for reprocessing.

   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
- > Products that are potentially contaminated must be disposed of

⚠ CAUTION

Improper cleaning

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

- > Use an automatic washer that meets the performance requirements of ISO 15883-1
- > Reprocess all detachable parts (such as light guide adapters)
- > Load the device with care: all contents must be rinsed and cleaned fully (no rinsing ‘blind spots’)
- > Ensure that the washer is properly maintained
- > Only use cleaning agents that are approved for the product
- > The devices must be pre-cleaned immediately after use and reprocessed within 6 hours
- > When pre-cleaning, do not use fixing temperatures in excess of 45 °C
- > When pre-cleaning, do not use fixing cleaning agents (active ingredients: Aldehyde, alcohol)

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 agents
- > After contact with chloride-based solutions, rinse products sufficiently with critical 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 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

In many countries, the qualifications required by personnel responsible for the reprocessing of medical devices are regulated by law.

In any event, 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 effectiveness of the following procedures:

- Manual cleaning
- Automated cleaning and thermal rinsing
- Steam sterilization
- Low temperature plasma sterilization (STERRAD® 100S, NX, 100NX)

as described in this document, has been fully validated.

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

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

Use only FDA-cleared materials and equipment for reprocessing.

4.4 The Process Flow

The product has to be prepared for reprocessing immediately after use by pre-cleaning.

Refer to *section 3.5* for pre-cleaning instructions.

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

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

The optimum and most reliable reprocessing results are achieved using automated cleaning 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.

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 Agents

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

- Cidezyme®/Enzol® (Johnson & Johnson)

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 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.

4.6 Manual Cleaning

4.6.1 Overview

Stage	Work step	Temperature (°C/°F)	Time (min)	Water quality	Cleaning 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	Final rinsing	< 45/113	≥ 1	Critical water	---
IV	Drying	---	---	---	---

Table 4-1: Overview of manual cleaning.

4.6.2 Performing Manual Cleaning

Complete stage I: Cleaning

Prepare the cleaning solution as per the manufacturer's instructions.

NOTICE! Damage resulting from rough handling. Handle the product with care. Do not knock or bend. Set down carefully.

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.

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

   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 minute** 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 minute** each.

   Use fresh water for each rinse.

   Allow residual water to drip off for a sufficient length of time.

Complete stage III: Final rinsing

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

   Allow residual water to drip off for a sufficient length of time.

Complete stage IV: 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 process if necessary.

   Immediately set aside any damaged products.

4.7 Automated Cleaning and Thermal Rinsing

4.7.1 Overview

Stage	Work step	Temperature (°C/°F)	Time (min)	Water quality	Cleaning solution / notes
I	Pre-rinsing	< 25/77	2	Drinking water	---
II	Cleaning	55/131	10	Drinking water	Alkaline detergent, e.g. 0.5 % neodisher® MediClean forte (5 ml/L), ph > 10
III	Rinsing I	> 10/50	1	Drinking water	---
IV	Rinsing II	> 10/50	1	Critical water*	---
V	Thermal rinsing	> 90/194	5	Critical water*	A_0 value > 3000
VI	Drying	---	---	---	---

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

** Critical water = according to AAMI TIR 34 (deionized water (DI), reverse osmosis (RO) treated)*

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 Rinsing

AUTOCLAVE

Thermal rinsing should be performed only for products that are labeled as autoclavable.

Use a legally marketed washer 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 rinsing. 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.

   Apply a validated loading plan when doing so.

   Follow the manufacturer's instructions and instructions for use for the device.

   When loading, take care to avoid creating rinsing blind spots.
4. Start the cleaning cycle in accordance with the manufacturer's instructions and instructions for use for the device.

⚠ **CAUTION!** Risk of scalding when unloading the device. Be sure to wear gloves.

5. Remove the reprocessed product from the washer.
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 process if necessary.

Immediately set aside any damaged products.

4.8 Sterilization

4.8.1 Performing Steam Sterilization

AUTOCLAVE

Steam sterilization should be performed only for products that are labeled as autoclavable.

Use critical water that meets the requirements of AAMI TIR 34.

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

⚠ **CAUTION!** Residue from cleaning agents and organic material can negatively influence the sterilization result. Perform the sterilization only on a properly cleaned and dried product.

1. Make sure that manual or automated cleaning and thermal rinsing is complete.
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.

⚠ **CAUTION!** Risk of scalding when loading the device. Wear suitable gloves.

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	270 °F (132 °C)
Holding time	at least 4 min (effective sterilization time)
Drying time	at least 30 min

Note: It is the responsibility of the operator to establish that the sterilizer used meets the parameters above.

⚠ **CAUTION!** Risk of scalding when unloading the device. Wear suitable gloves.

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.

4.8.2 STERRAD® Sterilization Process 100S, NX, 100NX

NOTICE! STERRAD® sterilization may result in cosmetic device changes that do not usually affect the device function.

NOTICE! The product must be completely dry before it can be sterilized in the STERRAD® sterilizer. Loads containing moisture may cause a cycle cancellation.

The STERRAD® Sterilization Systems, manufactured by Advanced Sterilization Products (ASP), use low-temperature, hydrogen peroxide gas plasma technology for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices.

Refer to the STERRAD® Sterilization Systems User Guide for detailed instructions for use of any STERRAD® unit, ASP's STERRAD® Sterility Guide (SSG) at www.sterradsterilityguide.com or contact ASP customer service.

Use only legally marketed reprocessing trays that are approved for STERRAD® sterilization. Observe the instructions for use of the tray.

1. Make sure that manual or automated cleaning is complete.
2. Place all parts in the reprocessing tray.
3. Place a STERRAD® indicator strip in the tray.
4. Seal the tray.
5. Double-wrap the tray with 2 single layers of legally marketed sterilization wrap.
6. Load the wrapped tray in the sterilizer.

   Position the tray so that the sterilization medium can act thoroughly on all areas. Do not allow any item to touch the wall of the sterilizer.
7. Start the sterilization cycle in accordance with the manufacturer's instructions and instructions for use for the sterilizer.

   STERRAD® sterilization was validated for the following cycles:

   - STERRAD® 100S Short Cycle
   - STERRAD® NX Standard Cycle
   - STERRAD® 100NX Standard Cycle
8. 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
Image cloudy	Glass surfaces soiled	Manual cleaning as per *section 4.6*, then reprocess, check the water quality
	Leaky, defective lens system	Send the endoscope in for repair
Image too dark, too little illumination	Glass surfaces soiled	Manual cleaning as per *section 4.6*, then reprocess, check the water quality
	Unsuitable light guide	Use a suitable light guide
	Light guide incorrectly attached to endoscope	Check that the light guide is seated properly
	Defective fiber optics	Check fiber optics as per *section 3.3*
	Defective light guide or light source	Check the light guide and light source
Image is yellowed	Soiled fiber optics	Manual cleaning as per *section 4.6*, then reprocess, check the water quality
	Light guide soiled or defective	Check the light guide (e.g. by illuminating a white surface)
Corrosion, staining, discoloration	Inadequate cleaning (e.g. remaining protein residue)	Manual cleaning as per *section 4.6*, if necessary, rub thoroughly, then reprocess
	Insufficient rinsing between the reprocessing stages, especially prior to sterilization	Rinse sufficiently between the reprocessing stages
	Excessive chloride concentration	Check water quality
	Excessive concentration of minerals (e.g. limescale) or organic substances	Check the water quality, only use demineralized water if necessary
	Heavy metal ions and/or silicates, elevated concentration of iron, copper, and manganese in the water or sterilizer steam	Check the water quality, only use demineralized water if necessary
	Contaminated, too frequently reused cleaning solution	The cleaning 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*)

Only ship devices that have been properly reprocessed.

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.	**11.0031a**
Direction of view	0°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible light

Item no.	**11.0041a**
Direction of view	45°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible light

Item no.	**11.0043a**
Direction of view	30°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible light

Item no.	**11.0055a**
Direction of view	0°
Field of view	Wide angle
Working length	312 mm
Outer diameter of insertion portion	5 mm
Transmission	visible light

Item no.	**11.0057a**
Direction of view	30°
Field of view	Wide angle
Working length	312 mm
Outer diameter of insertion portion	5 mm
Transmission	visible light

Endoscopes, optimized for use in conjunction with 4K/UHD camera systems:

Item no.	**11-0231a**
Direction of view	0°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible light

Item no.	**11-0243a**
Direction of view	30°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible light

Endoscopes, optimized for use in conjunction with NIR imaging systems designed for NIR fluorescence imaging:

Item no.	**11-0131nir**
Direction of view	0°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible and near-infrared light

Item no.	**11-0143nir**
Direction of view	30°
Field of view	Wide angle
Working length	344 mm
Outer diameter of insertion portion	10 mm
Transmission	visible and near-infrared light

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 (White light imaging)	+15 °C to +37 °C
Temperature (NIR fluorescence imaging)	+15 °C to +30 °C
Relative air humidity	5 % 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
	Endoscope light guide adapter, Wolf systems	05.0116b

Table 6-1: 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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