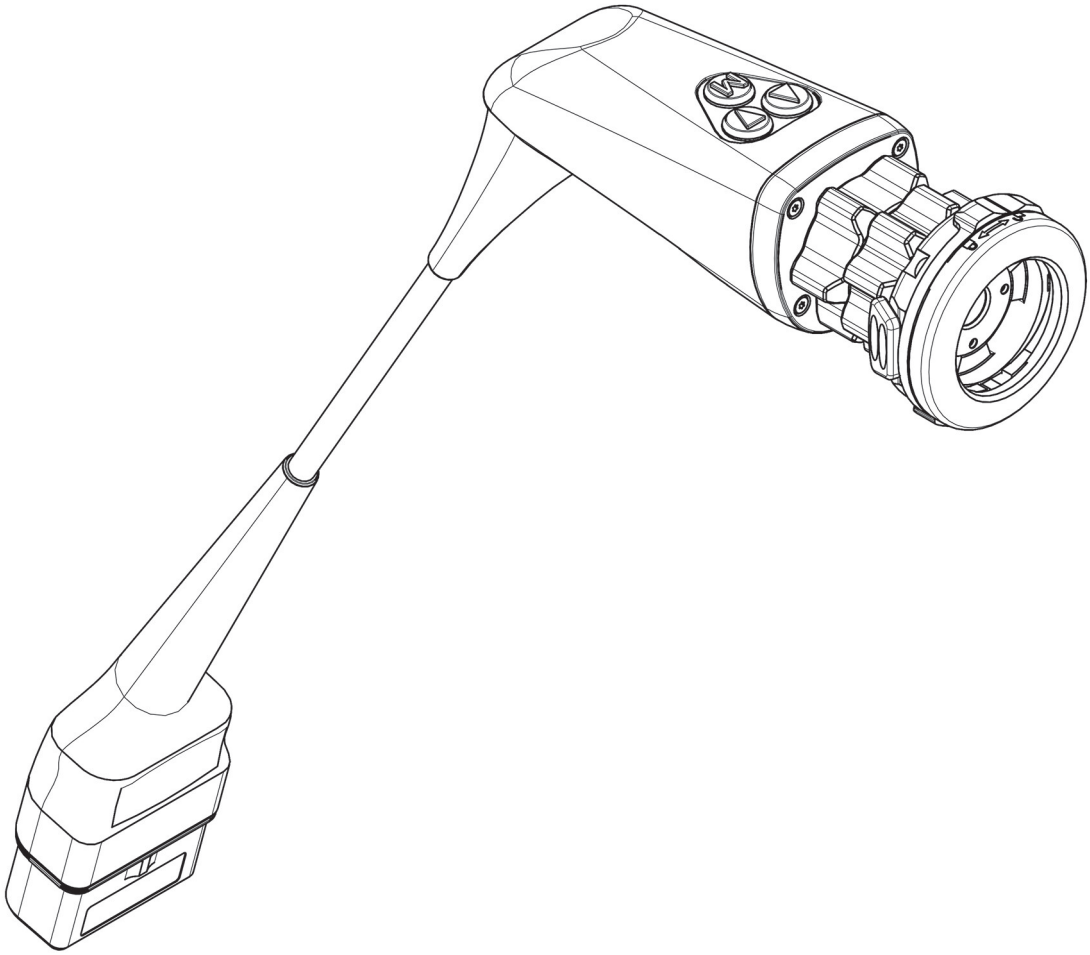
Instructions For Use

NIR FI Camera Head Full HD Zoom

Camera Head for NIR Fluorescence Imaging
(USA)



TPA866-000-01
Version: 0
22 - Jun - 2023

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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 product:

Item name:	**NIR FI Camera Head Full HD Zoom**
Item number:	**95-3908**

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.

0.2 Target Group

These instructions for use are intended for physicians, medical assistants, medical engineers and employees of central sterile supply who are entrusted with the installation, operation, maintenance, 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.

0.4 Supplementary Documents

Be sure to observe the instructions for use of the camera control unit (95-3981, 95-3985) in regards to the use and configuration options of the camera head buttons.

1 General Information about the Device

1.1 Scope of Delivery

The scope of delivery for the device includes:

- 1x camera head
- 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 your distributor. You will find contact details on the back of this document.

1.2 Product Description

1.2.1 Performance Characteristics and Function

Compatible controllers

The present camera head can be connected to the controllers with the following item numbers and is compatible with these only: 95-3981, 95-3985.

CMOS camera

The combination of camera head and camera control unit result in a camera based on CMOS technology that is used to provide endoscopic real-time video for display on a monitor.

NIR fluorescence

The camera head is sensitive in the visible and near-infrared spectrum to provide visualization of near-infrared light for NIR fluorescence imaging.

Full HD – 1080p

When used with a compatible monitor, the camera delivers a native full HD image resolution using progressive scanning (1080p).

Camera head buttons

The camera head features three fully programmable camera head buttons that can be used to control image display, record images or video, or to navigate and change the settings in the camera control unit's configuration menu.

Parfocal zoom

The camera head features a manually adjustable focal length of 14.25 – 28 mm, which corresponds to a 2x zoom.

The integrated objective is designed parfocally, so that the image remains sharp at any time.

1.2.2 Visual Overview

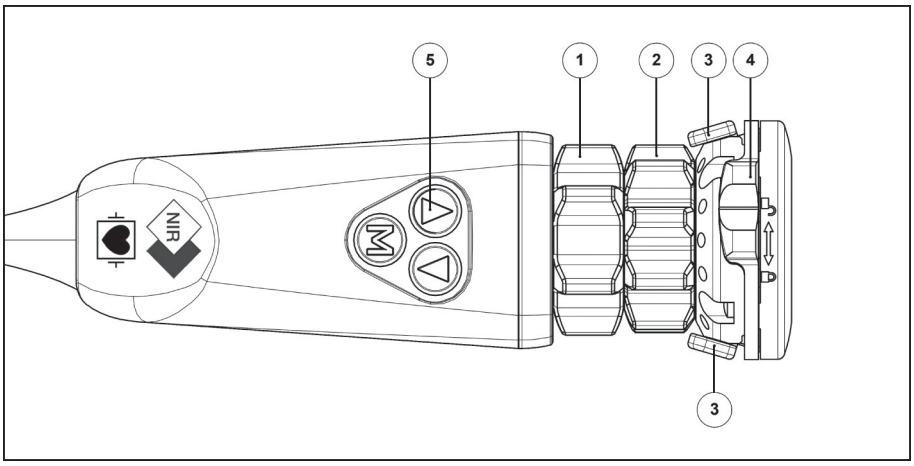


Figure 1-1: The “NIR FI Full HD Zoom” camera head model.

1. Zoom ring
2. Focusing ring
3. Eyepiece locking mechanism
4. Protection against inadvertent opening of the locking mechanism
5. Camera head buttons

1.3 Usage

1.3.1 Intended Use

The camera head is connected to a camera control unit and endoscope to provide real-time video during diagnostic or therapeutic endoscopic procedures.

The camera head is also used for intraoperative fluorescence imaging in the near-infrared range with a suitable fluorescence dye (principally Indocyanine Green) that promotes the fluorescing appearance of the camera image.

1.3.2 Indications

The camera head is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery whenever a laparoscope/endoscope/arthroscope is indicated for use.

A few examples of the more common endoscopic surgeries are:

- Laparoscopic cholecystectomy
- Laparoscopic hernia repair
- Laparoscopic appendectomy
- Laparoscopic pelvic lymph node detection
- Laparoscopically assisted hysterectomy
- Laparoscopic and thorascopic anterior spinal fusion
- Anterior cruciate ligament reconstruction
- Knee arthroscopy
- Small joint arthroscopy
- Decompression fixation
- Wedge resection
- Lung biopsy
- Pleural biopsy
- Dorsal sympathectomy
- Pleurodesis
- Internal mammary artery dissection for coronary artery bypass
- Coronary artery bypass grafting where endoscopic visualization is indicated
- Examination of the evacuated cardiac chamber during performance of valve replacement

The users of the camera head are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.

1.3.3 Contraindications

The use is contraindicated in all cases where endoscopic procedures are contraindicated for any reason.

There are no known contraindications linked directly to the devices.

Medical contraindications that are listed for suitable fluorescence dyes that may be used apply.

For any interventions the responsible physician must decide applying professional standards and based on the general condition of the patient and an individual benefit-risk analysis whether the intended application of the device is admissible.

1.3.4 User Profile

Intended to be used by trained healthcare professionals in a professional healthcare environment (hospital).

1.3.5 Compatibility with HF Surgical Devices

The device is approved for use in conjunction with HF surgical devices. Applying HF surgery does not alter the conditions of the intended use.

1.3.6 Components Required for Operation

The camera head can be connected to the camera control units with the following item numbers and is be compatible with these only:

- NIR FI CCU Full HD (95-3981)
- NIR FI CCU 4K (95-3985)

For the complete system requirements for achieving the intended results when using the camera for NIR fluorescence imaging, observe the instructions for use supplied with the light source (05-0761nir).

1.4 Conformity

1.4.1 Standards and Directives

The device consisting of controller and camera head meets the requirements of the following applicable standards:

- **IEC 60601-1** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2** Medical electrical equipment - Part 1-2: Electromagnetic compatibility
- **IEC 60601-2-18** Medical electrical equipment - Part 2-18: Particular requirements for basic safety and essential performance of endoscopic equipment

1.4.2 Protection against Electric Shock

In combination with the camera control unit the product meets the - defibrillation-proof type CF classification requirements according to IEC 60601-1 for protection against electric shock and is approved for use in combination with applied parts intended for direct conductive contact with the heart.

1.4.3 Medical Device Classification

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

1.5 Marking

1.5.1 Pictograms and Information on the Device and Packaging


Adhere to the instructions for use


CE marking

Item number

Serial number

Medical Device


Manufacturer


Date of manufacture


Caution (IEC 60601-1 3rd edition) /
Take note of accompanying documents (IEC 60601-1 2nd edition)

MR unsafe


Type CF defibrillation-proof applied part according to IEC 60601-1


Release


Lock


Permissible storage and transport temperature


Permissible relative air humidity during storage and transport


Permissible atmospheric pressure during storage and transport

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


Separate collection for WEEE (waste of electrical and electronic equipment)

1.5.2 Pictograms in this Document

General warning sign

Electricity hazard warning sign

Biohazard warning sign, risk of infection

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 your distributor.

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.

Keep the original packaging. Transport and store the product in its original packaging and use it to return goods if service support is required.

If you detect any faults or malfunctions, inform us immediately.

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! Risks from the arrangement, setup, combination, or properties of connected or surrounding devices or equipment. Follow the instructions for use of the respective devices. Perform a risk assessment.

WARNING! Risk of suffocation. Keep packaging material out of reach of children.

WARNING! Interference to the live image caused by electromagnetic disturbances (white light and NIR fluorescence imaging mode). Risk to the patient due to altered image representation, system locked in FI mode, live image failure (e.g. delay, frozen image), image interference (e.g. flickering, stripes), altered image orientation. Remove all sources of interference. Observe the recommended minimum distances according to the Information on Electromagnetic Compatibility. Ensure that the monitor is correctly displaying the live image. Ensure that the live image is displayed in the correct orientation (not mirrored).

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. Do not kink, crush or strongly bend camera cable. 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, user and other persons, or can lead to premature wearing of the device.

2.2.2 Staff Qualifications

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

3 Use

3.1 Safety Notices

⚠ 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

⚠ WARNING

Displaying a recorded image instead of the live image

Risk to the patient

> Ensure that the monitor is displaying the live image from the endoscopic camera at all times

⚠ WARNING

Interactions between devices in simultaneous use (e.g. lasers, electro-surgery)

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

> Ensure that all the devices in use meet at minimum the required type BF, CF or CF defibrillation-proof classification requirements 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

3.2 Camera Head Buttons

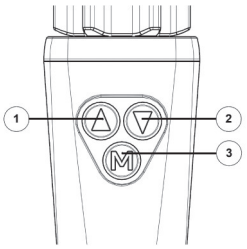
3.2.1 General Information and Default Button Settings

Each camera head button can be programmed to trigger different functions by tapping briefly or by holding down.

The buttons can be fully programmed in the menu, subject to the following restrictions:

- It is not possible to change the way in which the menu itself is opened;
- Certain functions (e.g. White balance, Light source on/off, Advanced Views and Noise reduction) can only be assigned to buttons 1 and 2, activated by holding down the button.

The **Default settings** for the camera head buttons are as follows:



	Button 1	Button 2	Button 3
Tap briefly	**Light source is on:** Toggle imaging modes **Light source is off:** Activate light source	Video capture start / stop	Take photo
Press and hold down	**NIR FI mode is on:** Directly return to white light imaging **White light imaging is on:** Deactivate light source	White balance	Open menu

Table 3-1: Default settings for the camera head buttons.

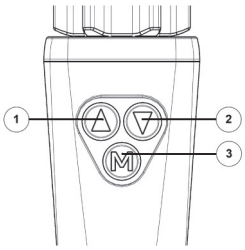
3.2.2 Changing the Function of Camera Head Buttons

Navigate in the menu with the arrow buttons and confirm your selection each time using the Menu button.

The following example describes how to program button 3 for edge enhancement.

1. Press the **Menu** button on the camera head for approx. 2 seconds.
   > *The main menu appears on the screen.*
2. Navigate to the **Options** menu item and select.
3. Navigate to **Button function** and select.
4. Navigate to **M short** and select.
5. Navigate to the **Edge enhancement** option and select.
   > Your selection is displayed in white type.
   > You can now use button 3 to control edge enhancement.

3.2.3 Navigating in the Menu using the Camera Head Buttons



Entry into menu:	Press and hold button 3.
Upwards in the menu:	Press button 1 briefly.
Downwards in the menu:	Press button 2 briefly.
Confirm selection in menu:	Press button 3 briefly.
Leave the menu:	Press and hold button 3.

3.3 Performing a Visual Inspection

*A visual inspection must be performed **prior to each medical procedure**.*

1. Check that the glass surfaces of the camera head are completely clean.

   To do this, direct the camera head onto a clean, white surface. If the glass is dirty, you will see spots or shadows on the screen that cannot be seen on the surface.

NOTICE! Scratching of the glass. Use a soft, lint-free wipe and not a brush.

Clean soiled glass surfaces with 70 % ethanol.

2. Check that the adjusting ring(s) is/are operational.

   It should be possible to rotate each ring without it catching.

   Every ring should respond to turning with slight, uniform resistance.

   Do not use the camera head if the adjusting ring catches when turned or is too loose.

3. Check that the camera cable is undamaged.

   Do not use the camera head if the camera cable is kinked, broken, or twisted.

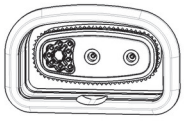
4. Check that the contacts on the camera cable connection plug are free from moisture and dirt.

   Do not use the camera head if there is any moisture in the plug or contacts are soiled.

5. Inspect the housing for external damage.

   Do not use the device if there is any external damage to the housing.

3.4 Connecting up the Camera Head



1. Slide the connection plug fully into the connection socket on the camera control unit until it clicks into place.

   > *The name of the connected camera head model is displayed on the screen.*

3.5 Connecting an Endoscope

All endoscopes with an ACMI-compatible eyepiece can be connected to the camera head.

1. Attach a sterile drape to the endoscope if necessary.

   If applicable, observe the instructions for use supplied with the sterile drape.

Note: The user is responsible at all times for maintaining the sterile barrier.

2. Press together the two locking mechanisms on the endocoupler to spread apart the retaining clips.
3. Insert the endoscope including the eyepiece cap and release the locking mechanisms.

4. Secure the endoscope against inadvertent opening. Use the locking device on the endocoupler to do so.
5. If applicable, draw the sterile drape over the camera head and camera cable toward the camera control until the drape is completely unfolded.

3.6 Adjusting the Image Focus and Zooming

1. Adjust the desired image size using the rear zoom ring.
2. Direct the endoscope at a structure with a sharp outline at the working distance.
3. Adjust the front focusing ring on the camera head until the image becomes sharp.

   Once the image focus is sharp, the image also remains sharp when zooming.

3.7 Stopping Usage and completing Pre-Cleaning

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

Note: The endocoupler is permanently attached to the camera head and cannot be detached.

1. Remove and discard the sterile drape, if present.
2. Uncouple the endoscope and the light guide.
3. Disconnect the camera head from the controller.
4. Switch off the electrical equipment.
5. Pre-clean the camera head including cable and plug 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.
6. Arrange for reprocessing.

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

3.8 Storage and Transport

Store the device in a dry, well-ventilated, temperature-controlled room, where it is protected from dust.

When placing into storage or storing temporarily, make sure that the device cannot be damaged by its surroundings.

To avoid damage, keep out of direct sunlight and away from radioactivity and strong electromagnetic radiation.

The ambient conditions for transport, storage, and operation are described in *section 5.2*.

3.9 Troubleshooting

Issue	Possible causes	Fixes
Image too dark, too little illumination	Glass surfaces on camera head are soiled	Clean glass surfaces (*chapter 4*)
	Stubborn residue on the glass surfaces	Remove residue (*chapter 4*)
	Light guide defective	Connect a new light guide. Send in for repair
	Camera brightness set too low	Increase camera brightness
	Endoscope optical system defective	If the image is too dark even without the camera, use a different endoscope and send in the endoscope for repair
	Light output set too dark	Increase the light output at the light source
No image on the monitor	Connection cable not connected or defective	Connect the camera head to the controller. Check the plug for moisture. If the cable is defective, send it in for repair

Table 3-2: Troubleshooting table.

3.10 Repair

Should you need to arrange a repair for the device, please contact one of our subsidiaries. Contact details can be found on the back of these instructions for use.

When you send in equipment, please enclose as accurate a **fault description** as possible, and record the item number and serial number of the product on the delivery note. You will find these details on the nameplate.

⚠ WARNING

Contaminated device

Risk of infection

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

> Clearly identify contaminated products as such

Send only thoroughly cleaned goods in for repair.

For shipping, please use the original packaging whenever 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.

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 product

> Use an automatic washer that meets the performance requirements of ISO 15883-1

> Load the washer 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

Improper sterilization

Risk of damage to the device

> Use only approved sterilization processes

> Do not sterilize camera head with steam or in an autoclave

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
- > Avoid contact with chloride-based solutions
- > If the products should come into contact with chloride-based solutions, rinse thoroughly with critical water and dry completely

NOTICE

Use of ultrasonic bath

Damage to the device

- > The product must not be exposed to the ultrasonic bath

Devices were investigated for device functionality after 300 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

If not using a sterile drape, you must employ the reprocessing procedure.

Reprocessing comprises the following steps

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

The procedures specified in this document were validated for efficacy.

Operator responsibility

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.

4.4 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.

Follow the manufacturer's instructions!

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

4.5 Manual Cleaning

4.5.1 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 agent: Cidezyme®/Enzol®, prepared as per manufacturer's instructions
II	Intermediate rinsing 2x	20-30 / 68-86	2 x ≥ 1	Drinking water	---
III	Final rinsing	20-30 / 68-86	3 x ≥ 1	Critical water*	---
IV	Drying	---	---	---	---

Table 4-1: Overview of manual cleaning.

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

4.5.2 Performing Manual Cleaning

⚠ WARNING

The product is not sterile after manual cleaning.

NOTICE

Scratch-sensitive surface

Risk of corrosion

Do not use metal brushes, metal objects, or abrasive cleaners. To remove soiling on optical surfaces, use pads soaked with alcohol or neutral cleaner only.

Note: Use fresh water for each rinse.

Note: The endocoupler is permanently attached to the camera head and cannot be removed.

Complete stage I: Cleaning

1. Pre-clean the camera head including cable and plug 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.
2. Completely immerse the product for **2 to 5 minutes** in the cleaning solution prepared as per manufacturer's instructions.

3. Make sure that the cleaning solution touches all accessible surfaces and that the product remains immersed throughout the entire cleaning time. When placing the product, ensure that all air escapes from the hidden crevices.
4. While the product is immersed in the cleaning solution, clean it using a soft, clean, lint-free wipe or with a soft bristled brush. Wipe or brush for at least **1 minute** or until no more residue can can be seen.
5. During the cleaning, maneuver mobile components of the completely immersed product in all directions as far as they will go **3 times**.
6. Thoroughly rinse all surfaces of the product with hidden crevices or complex geometries at least **5 times** with the cleaning solution. Use a disposable 50 ml syringe.

Complete stage II: Intermediate rinsing

1. Completely immerse the product in drinking water (20-30 °C / 68-86 °F). Fully rinse all accessible surfaces in **2 rinses** of at least **1 minute** each.
2. During the rinsing, maneuver mobile components in all directions as far as they will go **3 times**.
3. Thoroughly rinse all surfaces of the product with hidden crevices or complex geometries at least **3 times** with drinking water. Use a disposable 50 ml syringe.
4. Allow residual water to drip off for a sufficient length of time.

Complete stage III: Final rinsing

1. Completely immerse the product in critical water (20-30 °C / 68-86 °F) and rinse all accessible surfaces in **3 rinses** of at least **1 minute** each.
2. During the rinsing, maneuver mobile components in all directions as far as they will go **3 times**.
3. Thoroughly rinse all surfaces of the product with hidden crevices or complex geometries at least **3 times** with critical water. Use a disposable 50 ml syringe.
4. Allow residual water to drip off for a sufficient length of time.

Complete stage IV: Drying

1. Dry the product using a soft, lint-free wipe. Use medical-quality filtered compressed air (pmax = 0.5 bar) to dry the areas you cannot reach with the wipe.
2. Make sure the product is clean and undamaged. Repeat the cleaning process if necessary.

Visual inspection

If any damage is detected, set aside the product immediately.

4.6 Automated Cleaning and Thermal Rinsing

4.6.1 Performing Manual Pre-Cleaning

Manual pre-cleaning must be performed prior to automated cleaning.

> ***NOTICE***
>
> **Scratch-sensitive surface.**
>
> Risk of corrosion.
>
> Do not use metal brushes, metal objects, or abrasive cleaners. To remove soiling on optical surfaces, use pads soaked with alcohol or neutral cleaner only.

Note: Use fresh water for each rinse.

Note: The endocoupler is permanently attached to the camera head and cannot be removed.

1. Pre-clean the camera head including cable and plug 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.

   Before wetting the wipe with the enzymatic cleaning solution (Cidezyme®/Enzol®), it should be prepared per the manufacturer's instructions.
2. Completely immerse the product for **10 to 30 minutes** in an alkaline cleaning solution (neodisher® MediClean forte) prepared as per manufacturer's instructions.
3. Make sure that the cleaning solution touches all accessible surfaces and that the product remains immersed throughout the entire cleaning time. When placing the product, ensure that all air escapes from the hidden crevices.
4. While the product is immersed in the cleaning solution, clean it using a soft, clean, lint-free wipe or with a soft bristled brush. Wipe or brush for at least **1 minute** or until no more residue can can be seen.
5. During the cleaning, maneuver mobile components of the completely immersed product in all directions as far as they will go **3 times**.
6. Completely immerse the product in drinking water (20-30 °C / 68-86 °F). Fully rinse all accessible surfaces in **2 rinses** of at least **1 minute** each.
7. During the rinsing, maneuver mobile components in all directions as far as they will go **3 times**.

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

4.6.2 Overview

Stage	Work step	Temperature (°C/°F)	Time (min)	Water quality	Cleaning solution
I	Pre-rinsing	Cold	2	Drinking water	---
II	Cleaning	55/131	10	---	Alkaline cleaner: neodisher® MediClean forte, prepared as per manufacturer's instructions
III	Intermediate rinsing 1	per the equipment manufacturer's standard cycle	1	Drinking water	---
IV	Intermediate rinsing 2	per the equipment manufacturer's standard cycle	1	Drinking water	---
V	Thermal rinsing	90/194	5	Critical water (A_0 value: > 3000)	---
VI	Drying	High (98.8/210)	30	---	---

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

Note: Color anodized parts or plastic components may bleach out during automated cleaning.

4.6.3 Performing Automated Cleaning and Thermal Rinsing

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[1] *that are approved for automated cleaning and thermal rinsing. Observe the instructions for use of the tray.*

1. Place the camera head 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.

[1] *for automated cleaning validation the camera head was placed in a standard reprocessing tray (OM-1002-SY)*

4.7 Sterilization

4.7.1 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[1] *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 the camera head 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. STERRAD® 100S und STERRAD® 100NX: Load the wrapped tray on the top shelf of the sterilization chamber. The bottom shelf must be empty.

   STERRAD® NX: Load the wrapped tray on the bottom shelf of the sterilization chamber. The top shelf must be removed.

   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 (top shelf only)
   - STERRAD® NX Standard Cycle (bottom shelf only)
   - STERRAD® 100NX Standard Cycle (top shelf only)
8. Remove the reprocessed product from the sterilizer.

   Ensure that products remain sterile after reprocessing.

[1] *for sterilization validation the camera head was placed in a standard reprocessing tray (OM-1002-SY) that was double-wrapped in polypropylene wrap (Kimguard® KC400 Sterilization Wrap, Kimberly Clark, PC 68248)*

4.7.2 STERIS Sterilization Systems V-PRO®

NOTICE! STERIS 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 a STERIS sterilizer. Loads containing moisture may cause a cycle cancellation.

Validated STERIS Low Temperature Sterilization Systems: V-PRO®, V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, V-PRO® maX 2, V-PRO® 60, V-PRO® s2.

The V-PRO® Sterilization Systems, manufactured by STERIS, use low-temperature, hydrogen peroxide gas plasma technology for terminal sterilization of properly cleaned, rinsed, and dried reusable medical devices.

Refer to the instructions for use of your respective STERIS unit or contact STERIS customer service.

Use only legally marketed reprocessing trays[1] *that are approved for STERIS Low Temperature Sterilization. Observe the instructions for use of the tray.*

1. Make sure that manual or automated cleaning and thermal rinsing is complete.
2. Place the camera head in the reprocessing tray.
3. Place an indicator strip on the tray.
4. Seal the tray.
5. Double-wrap the tray with two single layers of legally marketed sterilization wrap.
6. Load the wrapped tray in the sterilizer as per a validated loading plan. Observe the instructions of the sterilizer manufacturer when doing so.
7. Start the STERIS Low Temperature Sterilization in accordance with the manufacturer’s instructions.
8. Remove the reprocessed product from the sterilizer.

   Ensure that products remain sterile after reprocessing.

[1] *for sterilization validation the camera head was placed in a standard reprocessing tray (OM-1002-SY) that was wrapped in two layers of polypropylene wrap (HALYARD* H600 ONE-STEP*)*

4.7.3 STERIS Sterilization SYSTEM 1E®

NOTICE! The product must be used directly after sterilization, as there is no way of storing it without losing its sterility.

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

Validated STERIS Sterilization Systems: SYSTEM 1E® Liquid Chemical Sterilant Processing System, SYSTEM 1® endo Liquid Chemical Sterilant Processing System.

The 1E® Sterilization Systems manufactured by STERIS use peracetic acid for sterilization (S40™ Sterilant Concentrate).

Refer to the instructions for use of your respective STERIS unit or contact STERIS customer service.

Use only legally marketed reprocessing containers[1] *that are approved for STERIS System 1E® Sterilization. Observe the instructions for use of the tray.*

1. Make sure that manual or automated cleaning and thermal rinsing is complete.
2. Place the camera head in the reprocessing container.
3. Place an indicator strip on the container. Follow the manufacturer’s instructions.
4. Load the container in the sterilizer as per a validated loading plan. Observe the instructions of the sterilizer manufacturer when doing so.
5. Start the STERIS System 1E® sterilization in accordance with the manufacturer’s instructions.
6. Remove the reprocessed product from the sterilizer.

   Ensure that products remain sterile after reprocessing.

[1] *for sterilization validation the camera head was placed in a dedicated reprocessing container (STERIS part numbers: C1220E, C1140E, C1160E)*

4.7.4 Ethylene Oxide Gas Sterilization

This product is validated for Ethylene Oxide Gas Sterilization and can be sterilized and aerated using the parameters given here. Observe the instructions for use of the sterilizer and the parameters appropriate to the institutional, local and national requirements.

Use only legally marketed reprocessing trays[1] *that are approved for Ethylene Oxide Gas Sterilization. Observe the instructions for use of the tray.*

1. Make sure that manual or automated cleaning and thermal rinsing is complete.
2. Place the camera head 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 Ethylene Oxide Gas Sterilization in accordance with the device manufacturer's instructions, using the following validated parameters:

Preconditioning	
Temperature	55 °C (131 °F)
Relative air humidity	70 %
Vacuum set points	0.09 bar (9 kPa)
Conditioning time	30 min
Sterilization	
Temperature	55 °C (131 °F)
Relative air humidity	70 %
Concentration (100 % EO)	735 mg/l
Conditioning time	3 hours
Aeration	
Aeration time	12 hours
Temperature	50 - 57 °C (122 - 135 °F)

WARNING! Toxic ethylene oxide residue. Risk to persons. Adhere to the full aeration time.

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

Note: Ethylene Oxide Gas Sterilization may result in cosmetic device changes that do not usually affect the device function.

7. Remove the reprocessed product from the sterilizer.

   Ensure that products remain sterile after reprocessing.

[1] *for sterilization validation the camera head was placed in a standard reprocessing tray (OM-1002-SY) that was wrapped in two layers of polypropylene wrap (HALYARD* H300 ONE-STEP*)*

5 Product Data

5.1 Technical Data

Dimensions incl. endocoupler (W x H x D)	45 x 46.5 x 149 mm
Outer diameter of endocoupler	52.1 mm
Weight incl. endocoupler	330 g without cable
Image sensor	1/3” CMOS, progressive scan
Resolution	1920 x 1080 pixels
Focal length	14.25 - 28 mm
Camera cable length	3.5 m
Degree of protection	IP X7
Applied part as per IEC 60601-1	Defibrillation-proof type CF

5.2 Ambient Conditions

Transport and storage conditions

Temperature	-20 °C to +70 °C
Relative air humidity	5 % to 95 %
Atmospheric pressure	50 kPa to 106 kPa

Operating conditions

Temperature	+10 °C to +35 °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 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.

The product is packed in a polypropylene (PP) plastic case (0.5 kg) with a polyurethane (PU) soft foam inlay (0.12 kg), polyethylene (PE) bags (0.02 kg) as well as a corrugated cardboard box (0.54 kg).

Any product carrying this symbol must be disposed of separately through dedicated electrical and electronic devices recycling. Within the EU, such disposal is taken care of by the manufacturer free of charge.

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