

STORZ

KARL STORZ—ENDOSKOPE

en **Instructions for use**
IMAGE1 S HX Camera Heads



ATTENTION:

USA CUSTOMERS: Please note the following content is not applicable to U.S. customers. U.S. instructions can be found here:

<https://www.karlstorz.com/>

CANADIAN CUSTOMERS: For the applicable instructions for use for Canadian customers, please access the instructions:

<https://www.karlstorz.com/>



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1 General information

1.1 Read the instructions for use

If the instructions for use are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions carefully and follow all the safety notes and warnings. The reprocessing instructions can be downloaded from www.karlstorz.com/ifu by entering the item number.
- ▶ Keep the instructions for use and reprocessing instructions in a safe place.

1.2 Read the instructions for use of compatible products

If the instructions for use of compatible products are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use of the compatible products carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions of the compatible products carefully and follow all the safety notes and warnings.

1.3 Scope

The products listed here may not yet be available in all countries due to differences in approval requirements.

This instruction manual is valid for:

White Light camera heads

Product name	Item number
IMAGE1 S HX	TH110
IMAGE1 S HX-P	TH111

1.4 General signs and symbols

The signs and symbols used in this document have the following meaning:

Practical tip

-  This sign refers to useful and important information.

Actions to be performed

Action to be carried out by several steps:

- ✓ Prerequisite that must be met before carrying out an action.
- 1. Step 1
 - ⇒ Interim result of an action
- 2. Step 2
 - ⇒ Result of a completed action

Actions in the case of a single step:

- ▶ Step 1

Actions in safety notes:

- ▷ Step 1
- ▷ Step 2

Lists

1. Numbered list
 - Unnumbered list, 1st level
 - Unnumbered list, 2nd level

1.5 Description of warning messages

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warnings use the following levels of danger:

⚠ WARNING

WARNING

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

⚠ CAUTION

CAUTION

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

NOTICE

NOTICE

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

2 Normal use

2.1 Intended use

White Light camera heads

White Light camera heads are intended to be used in combination with telescopes or microscopes, and camera control unit for acquiring medical imaging during diagnostic and surgical procedures.

White Light camera heads do not have body contact.

2.2 Indications

Camera heads are suitable for acquiring medical imaging that can be used for medical investigation and visualization during diagnostic and surgical interventions.

2.3 Contraindications

The medical devices are not used in body contact with the patient but acquiring medical imaging. Furthermore, there are no contraindications for the use of the medical devices directly associated with the product.

2.4 Clinical benefits

Camera heads are an important part of the visualization imaging chain, which indirectly visualizes the diagnostic or surgical field. The clinical benefit of camera heads is only provided with the entire imaging chain products, such as light source & cable, camera head, camera control unit and monitor. White-light camera heads acquire digital images of the diagnostic or surgical field, then transmit them to the camera control unit for further imaging processing and presenting. Advanced camera heads such as white-light and FI camera heads integrating filters for supporting imaging enhancement technology, which leads to efficient surgical performance and better surgical outcome.

2.5 Residual risks

No residual risks directly related to the product were identified.

2.6 Target user populations

The medical device may only be used by doctors and medical assistants with a relevant specialist qualification.

2.7 Patient population

There are no restrictions in terms of patient groups for this product.

3 Safety and warning

⚠ WARNING

Danger due to non-observance of warnings and safety notes

This chapter contains warnings and safety notes structured according to hazards and risks.

- ▷ Carefully read and observe all warnings and safety notes.
- ▷ Follow the instructions.

3.1 Serious incidents

A 'serious incident' includes incidents which, directly or indirectly, had, could have had or could have any of the following consequences:

- Death of a patient, user, or another person
- Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
- A serious threat to public health
- ▷ The manufacturer and appropriate authority must be notified of all serious incidents.

3.2 Correct handling and product testing

If the product is not handled correctly, patients, users, and third parties may be injured.

- ▷ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.
- ▷ Check that the product is suitable for the procedure prior to use.
- ▷ Check the product for the following properties, for example, before and after every use:
 - Functionality
 - Damage
 - Changes to the surface
 - In the case of several components: completeness and correct assembly
- ▷ Do not continue to use damaged products.
- ▷ Dispose of the product properly; see *Disposing of the product*.

3.3 Combination with other components

The use of unauthorized devices and components may result in injuries.

- ▷ Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.
- ▷ Ensure that all configurations comply with the requirements for medical electrical systems.
- ▷ Only combine the product with devices and components that the manufacturer has approved for combined use, see chapter *Possible combinations*.
- ▷ Only use devices and components that have standardized interfaces and do not breach the normal use of the product.
- ▷ Only make changes to the product if these changes are approved by KARL STORZ.

3.4 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties.

- ▷ Make sure that the plug is completely clean and dry.

3.5 Electromagnetic interference

Medical electrical devices are subject to special precautions regarding electromagnetic compatibility. If other devices (e.g., MRT, CT, diathermy, electrocautery, or RFID) emit electromagnetic radiation, the product's functionality may be impaired. High-frequency (HF) communication equipment can affect electrical medical devices and impair their performance.

- ▶ During installation and operation of the product, please take note of the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility*.

3.6 Hot components

The high level of light intensity produced by the light source may cause the distal end, the light connections, and adjacent components to heat up. This can cause burns to patients, users, and third parties.

- ▶ Set the output of the adjustable light sources to a level that is just high enough to ensure optimal illumination of the operating area.
- ▶ Prevent the distal end, light connections, and adjacent components from coming into contact with tissue and operating room accessories.

3.7 High light intensity

The high level of light intensity produced by the light source may lead to permanent eye damage or blindness, and may cause tissue and items facing the light output to heat up.

- ▶ Do not look into the light output.

3.8 Risk of injury due to HF instruments

The product offers no insulation against high-frequency voltages. Using HF instruments may injure the user or patient and damage the product.

- ▶ Never allow HF devices to come into contact with the product or system.

3.9 Failure of products

The product may fail during use.

- ▶ Have a replacement product ready for each application or plan for an alternative surgical technique.

4 Product description

4.1 Product overview



IMAGE1 S HX Camera Head (TH110)

- | | | | |
|---|--|---|--|
| 1 | Instrument coupler | 4 | Scroll up,
activate camera function |
| 2 | Focus ring | 5 | Call up menu,
select |
| 3 | Scroll down,
activate camera function | | |



IMAGE1 S HX-P Camera Head (TH111)

- | | | | |
|---|--|---|--|
| 1 | Instrument coupler | 4 | Scroll up,
activate camera function |
| 2 | Focus ring | 5 | Call up menu,
select |
| 3 | Scroll down,
activate camera function | | |

4.2 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the described products in this medium may not be available in all countries due to different regulatory requirements.

The product can be combined with the following components:

Camera Head	Camera Control Unit	LINK Module
TH110	IMAGE1 S CONNECT (TC200)	IMAGE1 S X-LINK (TC301)
TH111	IMAGE1 S CONNECT II (TC201)	
	TELE PACK + (TP101)	
	TELECAM C3 (TC100)	

Interface with other products

The product can be connected to endoscopes or adaptors via the eyepiece connection.

4.3 Technical data

Description	Value
Image sensor	1x 1/3" CMOS
Image format	16:9
Image refresh rate	50/60 Hz
Focal length	16 mm
Dimensions (L x W x H)	100 x 36 x 35 mm
Weight (without cable):	
TH110	130 g
TH111	142 g
Applied part type according to IEC 60601-1	CF

4.4 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier

Symbol	Meaning
	Consult the printed or electronic instructions for use
	Non-sterile
	Fragile, handle with care
	Temperature limit
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU regulations. A code number after the CE mark indicates the responsible notified body. The EU regulations relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.5 Ambient conditions

Transport conditions	
There are no special transport conditions for this product.	
Storage conditions	
Temperature	-10°C ... +60°C (14°F ... 140°F)
Operating conditions	
Temperature	5°C ... 35°C (41°F ... 95°F)
Relative humidity (non-condensing)	20–95%

5 Preparation

5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for possible damage.
3. In the case of damage, hidden defects, and short deliveries, document their nature and extent and contact the manufacturer or supplier immediately.

5.2 Reprocessing the product

- Reprocess the product in line with the reprocessing instructions before using it.

5.3 Assembling the product

The product has an integrated instrument coupler and an integrated telescope.

1. Rotate the outer ring of the coupler clockwise and insert the endoscope eyepiece.
2. If the endoscope is connected to a pendulum camera head, make sure that the pendulum lock is engaged.
3. Tighten the outer ring on the grasping mechanism.
4. Rotate the outer ring of the instrument coupler counterclockwise to tighten it.

5.4 Connecting the light cable

- Tighten the knurled screw on the light cable by a quarter turn to connect the light cable.



6 Application

6.1 Adjusting the focus

-  The displayed image can be impaired by intense laser light.
1. Ensure that the correct video image is displayed on the monitor before starting the procedure.
 2. Turn the focus ring to adjust the image sharpness on the camera lens.

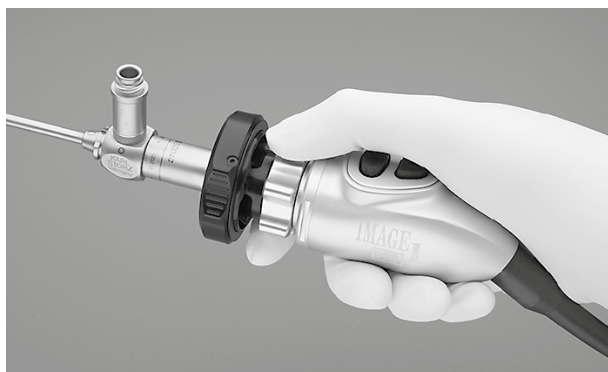


IMAGE1 S HX Camera Head (TH110)



IMAGE1 S HX-P Camera Head (TH111)

7 Maintenance, servicing, repairs, and disposal

7.1 Repairs to the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

- ▶ Please contact your local KARL STORZ subsidiary or authorized dealer (see the list of subsidiaries).

Contaminated devices may not be shipped. To prevent contact infections and airborne infections, products must first be decontaminated. KARL STORZ reserves the right to send back contaminated products.

7.2 Disposing of the product

The product meets the requirements of the Directive on Waste Electrical and Electronic Equipment (WEEE).

Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this product.

1. The product must be disposed of in accordance with the applicable national laws and regulations at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Contact KARL STORZ SE & Co. KG, a KARL STORZ branch or an authorized dealer to find out the address of the collection point in your area.

8 Accessories and spare parts

8.1 Accessories

 Not all articles are available in all regions.

Article	Order no.
Adaptor, autoclavable	533TVA
Dust cap for camera heads	6349190
Camera Cover, sterile, for single use, pack of 40	040112-40
Camera Cover, sterile, for single use, pack of 50	040113-50
Camera Cover, sterile, for single use, pack of 15	040114-15
Camera Cover, sterile, for single use, pack of 40	040115-40
Camera Cover, sterile, for single use, pack of 40	040169-40
Camera Cover, sterile, for single use, pack of 25	040170-25

9 Electromagnetic compatibility

The described product has been tested as a system with the following devices. Relevant electromagnetic compatibility (EMC) information can be found in the "Electromagnetic compatibility (EMC)" section of the instructions for use for the devices.

Device	Item number
IMAGE1 S CONNECT	TC200
IMAGE1 S CONNECT II	TC201
IMAGE1 S X-LINK	TC301
TELE PACK +	TP101
TELECAM C3	TC100

The EMC warning statements, precautions, notes, and emission and immunity limits specified in the instructions for use for the devices also apply to the product described in these instructions for use.

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