KARL STORZ — ENDOSKOPE

en **Instructions for use**
**Retromolar Intubation Endoscope**

10-2021



CE 0123

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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

This instruction manual is valid for:

| Product name | Item number |
|---|---|
| Retromolar intubation endoscope 5.0x40 | 10331B2 |
| Tube holder for ETT, inner diameter 5 mm | 10331BA |

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

## 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 safety notes or in the case of a single step:

- ▶ Step 1

**Lists**

1. Numbered list

– Unnumbered list, 1st level
  – Unnumbered list, 2nd level

# 2 Normal use

## 2.1 Intended use

**Retromolar intubation endoscope**

Non-flexible intubation endoscopes are used for endoscopic imaging of the respiratory tract and for positioning endotracheal tubes in anesthesia, intensive care and emergency medicine.

Non-flexible intubation endoscopes are invasive (natural body orifice) and meant for transient use.

**Tube holder**

Tube holders are used for fastening the endotracheal tube on the intubation endoscope. Tube holders with connection for O2 insufflation allow for the application of oxygen.

Tube holders are non-invasive and designed for transient use.

## 2.2 Indications

The medical devices are suitable for use during endoscopic examinations and treatments in anesthesia, intensive care and emergency medicine.

## 2.3 Contraindications

The medical devices must not be used for procedures in direct contact with the central nervous system (CNS) and central circulatory system.

Beyond that, there are no contraindications for the use of the medical devices directly associated with the product.

## 2.4 Target user populations

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

## 2.5 Patient groups

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

# 3 Safety

## 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.

▶ Do not leave broken-off components inside the patient.

▶ Do not overload the product with mechanical stress.

▶ Do not bend bent products back to their original position.

## 3.3 Working in the field of vision

Using the product outside the field of vision can cause injury to tissue or can damage the product.

▶ Only use the product in the field of vision.

## 3.4 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.

## 3.5 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.
- Set the output of the adjustable light sources to a level that is just high enough to ensure optimal illumination of the operating area.
- Make sure the light output is sufficiently far away from tissue and operating accessories.

## 3.6 Appropriate combination of endoscope and fiber optic light cable

If the fiber bundle diameter of the fiber optic light cable is too large, the endoscope light connection will heat up. This may cause damage to the endoscope.

If the fiber bundle diameter of the fiber optic light cable is too small, not enough light will enter the endoscope. This may mean that the operating area is not sufficiently illuminated.

- Use the endoscope with a fiber optic light cable that has an appropriate fiber bundle diameter, see chapter *Possible combinations*.

## 3.7 Unsterile product

The product is not sterile when delivered. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

## 3.8 Creutzfeldt-Jakob disease

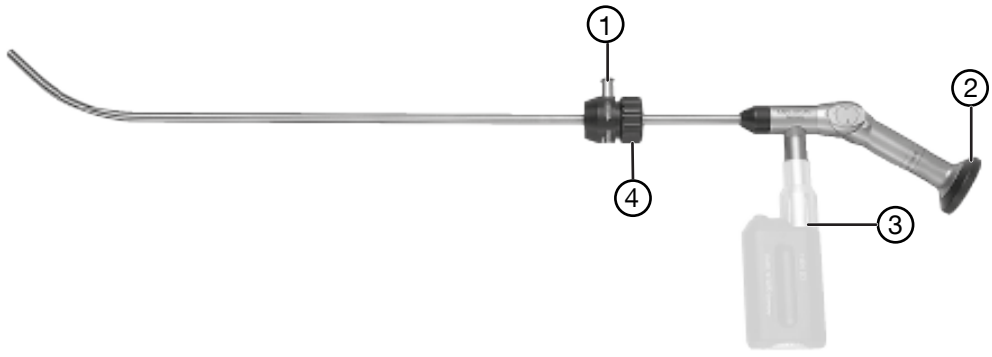
Products that come into contact with the central nervous system can become contaminated by organic residue containing prions. Prions lead to infection with Creutzfeldt-Jakob disease.

If Creutzfeldt-Jakob disease has been diagnosed or is suspected:

- Do not continue to use the product.
- Dispose of the product properly.

# 4 Product description

## 4.1 Product overview




| | | | |
|---|---|---|---|
| 1 | Connection for $O_2$ insufflation | 3 | Light inlet socket (with battery light source mounted) |
| 2 | Eyepiece | 4 | Tube holder |

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

The product can be combined with the following components:

| Product name | Item number |
|---|---|
| Adaptor | 495F |
| | 495G |
| LED battery light source | 11301D1 |
| | 11301D3 |
| | 11301D4 |
| | 11301DE |
| | 11301DF |

## 4.3 Technical data

**10331B2**

| Designation | Value |
|---|---|
| Working length | 390 mm |
| Max. insertion width | 5 mm |
| Angle of image field | 96° |
| Direction of view | 0° |
| Color code | Green |

Data in product descriptions and catalog texts refer to commonly used nominal values and may differ from the actual values in the technical data. The values are partially rounded.

## 4.4 Symbols on the packaging

| Symbol | Meaning |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|  | Medical device |
|  | Article no. |
|  | Batch code |
|  | Number of products in the product packaging |
|  | Unique Device Identifier |
|  | Consult the printed or electronic instructions for use |
|  | Fragile, handle with care |
|  | Not MR safe |
|  | Federal (USA) law restricts this device to sale by or on the order of a physician. |
|  | CE marking<br>With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body.<br>The EU legislation relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ. |

## 4.5 Ambient conditions

There are no special transport and storage conditions for this product.

# 5 Preparation

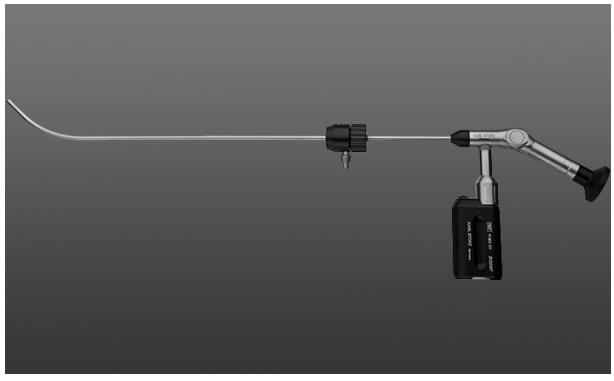
## 5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for missing items and any 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.

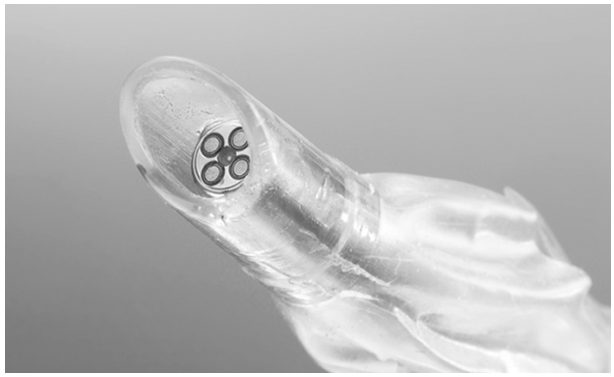
## 5.2 Assembling the product

ⓘ The adaptor (495G and/or 495F) may need to be unscrewed from the light inlet socket depending on which battery light source is used.

1. Screw the LED battery light source onto the light inlet socket.
2. Fit the tube holder to fix the tube in place during intubation.
3. Fix the tube holder in place by turning the knurled screw clockwise.



ⓘ The tip of the endoscope must always be covered by the endotracheal tube during intubation.



# 6 Disassembly

## 6.1 Disassembling the product

1. Turn the knurled screw counterclockwise and remove the tube holder from the product.
2. Unscrew the battery light source from the light inlet socket.

# 7 Maintenance, servicing, repairs, and disposal

## 7.1 Repairing the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ. The interventions described in this instruction manual are exempt from this rule.

- ▶ 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

For disposal, the following measures are necessary:

1. Decontaminate the products prior to disposal.
2. Country-specific national laws and regulations must be observed.

# 8 Accessories and spare parts

## 8.1 Accessories

| Item | Order no. |
|---|---|
| Tube holder for ETT, inner diameter 5 mm | 10331BA |

## 8.2 Spare parts

| Item | Order no. |
|---|---|
| Adaptor | 495F |
| Screw base | 495G |

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