

# STORZ

KARL STORZ — ENDOSKOPE

en **Instructions for use**  
**Tubing set**



11-2021

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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](http://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:

|                                    |           |
|------------------------------------|-----------|
| Tubing Set, irrigation, PC         | 031523-10 |
| Tubing Set, irrigation, FC         | 031524-10 |
| Tubing Set, irrigation, CV         | 031529-10 |
| Tubing Set, irrigation, UD         | 031531-10 |
| Tubing Set, suction, DS            | 030647-10 |
| Tubing Set, suction, BS            | 031647-10 |
| One-Day Tubing Set, irrigation, PC | 031563-10 |
| One-Day Tubing Set, irrigation, FC | 031564-10 |

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

## **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 purpose

**Tubing Set 031523-10, 031524-10, 031563-10, 031564-10:**

Tubing sets for irrigation are used to transport irrigation fluids to the irrigation instrument. Tubing sets for irrigation are non-invasive and are designed for short-term use.

**Tubing Set 031529-10:**

Tubing sets for cleaning are used to clean and remove fluids from the lens. Tubing sets for cleaning are non-invasive and are designed for short-term use.

**Tubing Set 031531-10:**

Tubing sets for cooling are used to transport and, where applicable, pump irrigation fluid to the irrigation instrument as well as to cool the instrument. Tubing sets for cooling are non-invasive and are designed for short-term use.

**Tubing Set 030647-10, 031647-10:**

Tubing sets for suction are used to transport fluid, tissue/particles, and gases from the patient to the collection system. Tubing sets for suction do not come into contact with the body.

### 2.2 Indications

The use of these tubing sets does not depend on particular indications. They serve as accessories and are used whenever fluids need to be transported, or whenever the associated KARL STORZ medical device is used.

### 2.3 Contraindications

They must not be used on patients who are not part of the defined patient group, or if the operation itself is contraindicated.

### 2.4 Intended application areas

**Tubing Set 030647-10:**

Gynecology, urology, arthroscopy

**Tubing Set 031523-10, 031563-10:**

Arthroscopy, urology, hysteroscopy, vertebral column

**Tubing Set 031524-10, 031564-10:**

Laparoscopy, proctology, thoracoscopy, laparoscopic gynecology, laparoscopic urology, gastroenterology

**Tubing Set 031529-10:**

ENT/NEURO: lens irrigation, e.g., during FESS

**Tubing Set 031531-10:**

ENT/NEURO, vertebral column

**Tubing Set 031647-10:**

Urology

### 2.5 Target user populations

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

## 2.6 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 Sterile product

The product is a sterile product. Special measures must be put in place to maintain its sterility. Otherwise, there is a risk of infection for the patient.

- ▶ Do not remove the sterile packaging until immediately before using the product.
- ▶ Check the product expiration date before use.
- ▶ Check the product packaging for damage before use.

If the expiration date has passed or if the packaging is damaged, the sterility of the products can no longer be guaranteed.

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

### 3.4 Disposable products

Disposable products are no longer safe after use. If disposable products are used again, there is a risk of infection and injury for patients, users, and third parties.

- ▶ Do not reprocess disposable products.
- ▶ Dispose of disposable products properly after use.

### **3.5 Correct storage**

Sterile products can be contaminated from incorrect storage. This creates a risk of infection for patients, users and third parties.

- ▶ Store products in their sterile packaging.
- ▶ Do not remove the products from the packaging until immediately before use.

### **3.6 Combination with other components**

Combination of the product with non-suitable instruments and devices can result in uncontrolled behavior and injury to patients, users, and third parties.

- ▶ Only combine the device with instruments and equipment that are approved for joint use.
- ▶ Only use approved accessories.

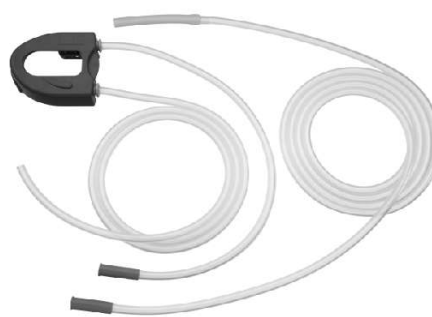
### **3.7 Failure of products**

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



### 4.2 Scope of supply

The scope of supply consists of 10 pieces (item number xxxxxx-10) of the tubing set.

### 4.3 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.

| Tubing set                                       | Compatible devices  |
|--|---|
| 031523-10<br>031524-10<br>031563-10<br>031564-10 | KARL STORZ ENDOMAT Select UP 210<br>KARL STORZ HAMOU ENDOMAT 26331120<br>KARL STORZ ENDOMAT SELECT UP 220 |
| 031529-10<br>030647-10<br>031647-10              | KARL STORZ ENDOMAT Select UP 210<br>KARL STORZ ENDOMAT SELECT UP 220                                      |
| 031531-10  | KARL STORZ ENDOMAT SELECT UP 220  |






| Tubing set  | Other compatible products                              |   |  |  |
|---|--|---|--|--|
| 031523-10<br>031524-10<br>031563-10<br>031564-10<br>031529-10 | Bag systems for irrigation solutions for spikes        |   | Instruments for irrigation with connection for tubes | n/a  |
| 030647-10<br>031647-10  | Instruments for suction with connection for tubes      | n/a<br>Ultrasonic transducer (KARL STORZ item no. 27610030) | Collection container                                 | n/a<br>Suction bottle (KARL STORZ item no. 20300051) with sealing cap (KARL STORZ item no. 20300039) |
| 031531-10   | Handpieces (e.g., shaver handpieces, drill handpieces) | Motors (e.g., High-Speed Micro Motor)                       |  |  |














When combining with other products, ensure that the planned use does not conflict with the normal use. This can be found in the documentation accompanying the individual products.

## 4.4 Technical specifications

| Tubing set for irrigation |  |
|---------------------------|--|
| 031523-10                 | Length to irrigation bag approx. 1,500 mm<br>Length to irrigation instrument approx. 2,650 mm<br>Smallest diameter approx. Ø 6.0 mm  |
| 031524-10                 | Length to irrigation bag approx. 1,800 mm<br>Length to irrigation instrument approx. 2,650 mm<br>Smallest diameter approx. Ø 6.0 mm  |
| 031529-10                 | Length to irrigation bag approx. 1,500 mm<br>Length to irrigation instrument approx. 2,650 mm<br>Smallest diameter approx. Ø 1.5 mm  |
| 031531-10                 | Length to irrigation bag approx. 1,500 mm<br>Length to irrigation instrument approx. 2,650 mm<br>Smallest diameter approx. Ø 1.5 mm  |
| Tubing sets for suction   |  |
| 030647-10                 | Length to suction instrument approx. 2,650 mm<br>Length to collection container approx. 1,500 mm<br>Smallest diameter approx. Ø 6.0 mm   |
| 031647-10                 | Length from patient to suction bottle approx. 2,650 mm<br>Length to suction bottle approx. 500 mm<br>Length to collection container approx. 1,500 mm<br>Smallest diameter approx. Ø 6.0 mm |
| One-day tubing sets       |  |
| 031563-10                 | Length to irrigation bag approx. 1,500 mm<br>Length to patient tube approx. 300 mm<br>Smallest diameter approx. Ø 6.0 mm   |
| 031564-10                 | Length to irrigation bag approx. 1,800 mm<br>Length to patient tube approx. 300 mm<br>Smallest diameter approx. Ø 6.0 mm   |

## 4.5 Symbols on the packaging

| Symbol  | Meaning             |
|---|---------------------|
|  | Manufacturer        |
|  | Date of manufacture |
|  | Medical device      |
|  | Article no.         |
|  | Batch code          |

| Symbol  | Meaning   |
|---|---|
|    | Number of products in the product packaging   |
|    | Unique Device Identifier  |
|    | Consult the printed or electronic instructions for use  |
|    | Keep away from sunlight   |
|    | Keep dry  |
|    | Use-by date   |
|    | Do not use if package is damaged.   |
|  | Do not resterilize  |
|  | Do not reuse  |
|  | Sterilized using ethylene oxide   |
|  | Individual sterile barrier system   |
|  | 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 directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ. |

## 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 Inspecting product

Check the following points before every use of the product:

- Validity of expiration date
- Damage to packaging
- Functionality of product
- Functional reliability and proper condition of the system used

### 5.3 Inserting the tubing set

**⚠ WARNING**

**Expiry date passed! Risk of infection!**

- ▶ Check the expiry date.
- ▶ Check the packaging for damage.
- ▶ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

**⚠ WARNING**

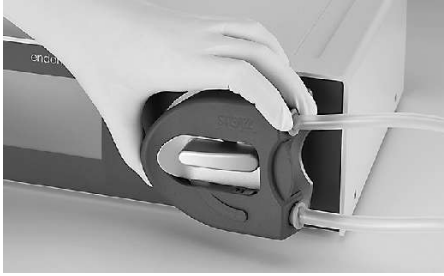
**Non-sterile product! Risk of infection!**

- ▶ Do not remove the product from the sterile packaging until immediately before use.

**⚠ WARNING**

**Improper assembly! Risk of contamination!**

- ▶ The product (at the patient end) must be assembled in the sterile area.
- ① The product is packaged individually in protective packaging, sterilized with ethylene oxide, and is intended for single use on a single patient. Otherwise there is a risk of cross-contamination.  
The one-day tubing sets 031563-01 and 031564-01 do not have to be changed after each patient. However, they may only be used in the roller pump for a maximum of 12 hours.
- ① The pressure transducer of the device is located under the pump roller so that the tubing set can only be inserted in one direction.



1. Place the tubing set on the pressure transducer of the device.



2. Shift the pump roller lever to the vertical position to fix the cassette in place.

## 5.4 Connecting tubing set

### 031523-10/031524-10/031529-10/031531-10/031563-10/ 031564-10 to the irrigation bag

#### **⚠ WARNING**

**Contaminated irrigation fluid! Risk of injury!**

- ▶ Make a clean cut through the membrane.
- ⓘ When the second inflow tube is not in use, close the clamp so that no air can escape into the irrigation system.
- ⓘ Following use and prior to disposal of the tubing set, place the protective caps back onto the spikes.

1. Remove the protective cap.



2. Puncture the irrigation bag with the spike.
3. Before use, vent the tubing set by allowing irrigation fluid to flow until no more air bubbles are in the system.



## 5.5 Connecting tubing set 031523-10/031524-10 to the irrigation instrument



1. Connect the silicone end to the irrigation instrument.
2. Before use, vent the tubing set by allowing irrigation fluid to flow until no more air bubbles are in the system.

## 5.6 Connecting tubing set 031563-10/031564-10 to patient tube 031162-10

1. Remove the protective cap from the LUER.



2. Connect the LUER to patient tube 031162-10.
  3. Before use, vent the tubing set by allowing irrigation fluid to flow until no more air bubbles are in the system.
- i** Upon completion of the operation, remove the patient tube 031162-10 from the one-day tubing set. Seal the one-day tubing set using the sterile sealing cap enclosed with the patient tube in order to protect the one-day set from contamination with each new patient.

## 5.7 Connecting tubing set 031529-10 to the CLEARVISION suction and irrigation sheath

1. Connect the tube end to the CLEARVISION suction and irrigation sheath.
2. Before use, vent the tubing set by allowing irrigation fluid to flow until no more air bubbles are in the system.

## 5.8 Connecting tubing set 031531-10 to the handpiece/ motor

1. Connect the tube end to the handpiece/motor connection.



2. Before use, vent the tubing set by allowing irrigation fluid to flow until no more air bubbles are in the system.

## 5.9 Connecting tubing set 030647-10 to the suction instrument and the collection system

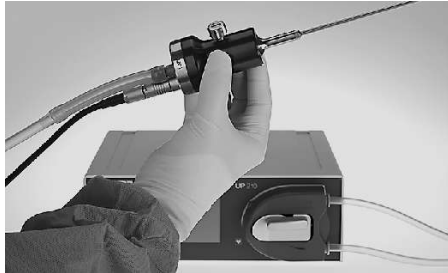


1. Place the silicone tube on the suction instrument



2. Connect the free end of the suction tube labeled "waste" to the collection container.

## 5.10 Connecting tubing set 031647-10 to the ultrasonic transducer and the suction bottle



1. Attach the silicone tube of the additional tubing set to the ultrasonic transducer.
2. Connect the other end to the suction bottle.



3. Connect the short end of the tubing set for the pump to the suction bottle and guide the free end labeled "waste" to the collection container.

## 6 Application

### 6.1 Using the tubing set

**⚠ WARNING****Disposable products! Risk of infection!**

The reprocessing of disposable products can lead to infections in patients, users and third parties as well as damage to the product.

- ▶ Never reprocess disposable products.
- ▶ Dispose of disposable products in accordance with the applicable regulations.

**⚠ WARNING****Kinks in the tube can restrict or prevent the flow!**

- ▶ Do not bend tubes.

**NOTICE****Pulling too hard! Risk of tearing!**

If the tube is pulled too hard, splice areas may tear.

- ▶ Do not strain the tube.

- ⓘ The one-day tubing set can be used for several operations and does not have to be replaced for each patient. However, it may only be used in the roller pump for a maximum of 12 hours.  
If the device remains switched on between operations, the one-day tubing set can remain in the pump fully assembled.  
After removing the pump tube from the roller pump, the one-day tubing set must not be used again.

- ⓘ The patient tube 031162-01 serves as a disposable tubing set for use with the one-day tubing set. The use of the patient tube 031162-01 is limited to one patient only.

## 7 Reprocessing

### 7.1 Reprocessing of the tubing set

This product must not be reprocessed and/or resterilized.

**⚠ WARNING**

**Disposable products! Risk of infection!**

The reprocessing of disposable products can lead to infections in patients, users and third parties as well as damage to the product.

- ▶ Never reprocess disposable products.
- ▶ Dispose of disposable products in accordance with the applicable regulations.

**i** One-day tubing sets are not for single use but must not be reprocessed under any circumstances.

## 8 Transport and storage

### 8.1 Storage conditions

Store in the original packaging. Protect against moisture and direct and indirect sunlight or any other form of UV radiation.

**NOTICE**

**The packaging or product may be damaged due to improper storage!**

- ▶ Do not place any objects on the product or the packaging.
- ▶ Do not store in the proximity of chemicals, disinfectants or radioactive emissions.

## 9 Maintenance, servicing, repairs, and disposal

### 9.1 Disposing of the product

For disposal, the following measures are necessary:

1. After use, transfer the products to a disposal process that is secure, controlled, monitored, and documented.
2. Country-specific national laws and regulations must be observed.

## 10 Subsidiaries

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