Instructions for use
Flexible Video Uretero-rensroscope FLEX-XC1
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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.
► Keep the instructions for use in a safe place.

1.2 Read the instructions for use of combinable 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.

1.3 Scope

This instruction manual is valid for:

<table>
<thead>
<tr>
<th>Product name</th>
<th>Item number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>KS06140-01</td>
</tr>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>KS06140-02</td>
</tr>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>091271-01</td>
</tr>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>091271-06</td>
</tr>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>091279-01</td>
</tr>
<tr>
<td>Video Uretero-Renoscope FLEX-X$^C_1$</td>
<td>091279-06</td>
</tr>
</tbody>
</table>

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
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

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

⚠️ CAUTION

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

NOTICE

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

2.1 Intended use

Flexible video uretero-renoscopes are used for imaging. Flexible video uretero-renoscopes with integrated working channel additionally allow for the use of flexible auxiliary instruments. Flexible video uretero-renoscopes are surgically invasive and are designed for short-term use.

2.2 Indications

The medical devices are suitable for use during endoscopic procedures in the upper urinary tract.

2.3 Contraindications

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

For patients under 5 kg (11 lbs), a maximum application time of 60 minutes must not be exceeded.
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.

1. Carefully read and observe all warnings and safety notes.
2. 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.
- 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 Combination with other components

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

- Only make changes to the product if these changes are approved by KARL STORZ.

3.4 Modifications to the product

Modified products can result in injury to patients, users, and third parties.

- Do not make any modifications to the product. Modifications to the product are not permitted.
3.5 Hot components
The high level of light intensity may cause the distal end of the endoscope to heat up. This can cause burns to patients, users, and third parties.
- Avoid contact with the distal end of the endoscope.

3.6 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 of the endoscope to heat up.
- Do not look into the light output of the endoscope.
- Make sure the light output of the endoscope is sufficiently far away from tissue and operating accessories.

3.7 Patient leakage current
If several products supplied with energy are used simultaneously, the patient leakage currents of the product can accumulate. Excessively high leakage current levels may result in the patient becoming injured.
- Only use products of the same type together, particularly if CF products are required.
  - If the product is connected to a type BF generator, the product will also correspond to type BF.

3.8 Danger from electrical current
Live applied parts can injure patients and users if there is unintentional contact.
- Check the insulation for damage before each use.
- If the insulation is damaged or missing: Do not use the products.
- Do not place live applied parts on the patient.
- Do not let live applied parts come into contact with conducting objects such as instruments, accessories, or liquids.
- Switch off the endoscope before putting it down, and do not place it in the vicinity of the patient (as per IEC 60601-1-1).

3.9 Risk of injury due to HF instruments
The product offers no insulation against high-frequency voltages. Using HF instruments may injure the patient and damage the product.
- Do not use the product while using HF instruments.

3.10 Malfunction
If the flexible videoendoscope is used while malfunctioning, the patient can be injured.
- Discontinue use immediately.
- Place the distal end of the videoendoscope in the straight position.
- Release the deflection lever.
- Remove the videoendoscope slowly and carefully from the patient.
3.11 Residual gases that are hazardous to health

Residual gases (EO, ECH) which are hazardous to health may remain in the product due to the sterilization process.

- Do not use the product on patients with a body weight under 1.5 kg (3.3 lbs).

3.12 Observing ambient conditions

If the device is stored, transported, operated or reprocessed under unsuitable conditions, patients, users or third parties may be injured and the device can be damaged.

- Observe the ambient conditions listed in the instructions for use and reprocessing.

3.13 Sterile product

The product is a sterile product. If the sterile barrier system is damaged, there is a risk of infection.

- Do not remove the sterile barrier system until immediately before using the product.
- Check the product expiration date before use.
- Visually inspect the sterile barrier system of the product for damage before each use (e.g., open seals, cracks, holes, discolorations). The inspection should be carried out with normal or corrected visual acuity in a sufficiently bright environment at a distance of 30 to 45 cm.

If the expiration date has passed or if the sterile barrier system is damaged, the sterility of the product can no longer be guaranteed.

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

3.14 Single-use product

The product must only be used once. Using the product more than once exposes patients, users, and third parties to a risk of infection and injury.

- Dispose of the product properly after using it once. Do not continue to use it.
4 Product description

4.1 Product overview

1 Distal tip
2 Deflection lever
3 Handle
4 Connector
5 Sheath
6 Bend protection
7 Luer connections

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.

<table>
<thead>
<tr>
<th>Product name</th>
<th>Item number</th>
</tr>
</thead>
<tbody>
<tr>
<td>E-BOX</td>
<td>TC028, TP012</td>
</tr>
<tr>
<td>IMAGE1 S X-LINK</td>
<td>TC301</td>
</tr>
<tr>
<td>C-MAC</td>
<td>8403ZX</td>
</tr>
<tr>
<td>C-HUB II</td>
<td>20290320</td>
</tr>
<tr>
<td>TELE PACK +</td>
<td>TP101</td>
</tr>
<tr>
<td>Stone Basket</td>
<td>27023LB</td>
</tr>
<tr>
<td>Fiber Fixation</td>
<td>11014Y</td>
</tr>
<tr>
<td>Endoscopic Seal</td>
<td>100010-10</td>
</tr>
</tbody>
</table>
The flexible video uretero-renoscope can be combined with laser fibers.
Tuohy Borst adaptors (100040-10) are medical devices that are used to insert catheters or optical fibers of 0 to 6 Fr. and also prevent the backflow of fluid around an instrument inserted through the working channel of flexible and rigid ureteroscopes.

Irrigation tubes can be connected to the flexible video uretero-renoscope via the Luer-Lock connection.

4.3 Technical data

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direction of view</td>
<td>0°</td>
</tr>
<tr>
<td>Angle of view</td>
<td>105°</td>
</tr>
<tr>
<td>Working length</td>
<td>70 cm</td>
</tr>
<tr>
<td>Outer diameter</td>
<td>9 Fr.</td>
</tr>
<tr>
<td>Diameter of working channel</td>
<td>3.5 Fr.</td>
</tr>
<tr>
<td>Deflection</td>
<td>up 270°, down 270°</td>
</tr>
</tbody>
</table>

4.4 Symbols on the packaging

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="manufacturer.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
</tr>
<tr>
<td><img src="date.png" alt="Date of manufacture" /></td>
<td>Date of manufacture</td>
</tr>
<tr>
<td><img src="md.png" alt="Medical device" /></td>
<td>Medical device</td>
</tr>
<tr>
<td><img src="ref.png" alt="Article no." /></td>
<td>Article no.</td>
</tr>
<tr>
<td><img src="lot.png" alt="Batch code" /></td>
<td>Batch code</td>
</tr>
<tr>
<td><img src="qty.png" alt="Number of products in the product packaging" /></td>
<td>Number of products in the product packaging</td>
</tr>
<tr>
<td><img src="udi.png" alt="Unique Device Identifier" /></td>
<td>Unique Device Identifier</td>
</tr>
</tbody>
</table>
### Symbol | Meaning
--- | ---
[Image of information symbol] | Consult the printed or electronic instructions for use
[Image of sun symbol] | Keep away from sunlight
[Image of drop symbol] | Keep dry
[Image of clock symbol] | Use-by date
[Image of cross symbol] | Do not use if package is damaged.
[Image of cross symbol] | Do not resterilize
[Image of cross symbol] | Do not reuse
[Image of sterile symbol] | Sterilized using ethylene oxide
[Image of oval symbol] | Individual sterile barrier system
[Image of oval symbol] | Individual sterile barrier system within protective packaging
[Image of Rx symbol] | Federal (USA) law restricts this device to sale by or on the order of a physician.

#### 4.5 Ambient conditions

| Storage conditions | Temperature: 5°C ... 25°C (41°F ... 77°F) |
| Transport conditions | Temperature: -30°C ... +50°C (-22°F ... +122°F) |
### Operating conditions

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>10°C ... 40°C (50°F ... 104°F)</td>
</tr>
<tr>
<td><strong>Relative humidity</strong></td>
<td>15–80%</td>
</tr>
<tr>
<td>(non-condensing)</td>
<td></td>
</tr>
<tr>
<td><strong>Max. operating altitude</strong></td>
<td>3,000 m</td>
</tr>
</tbody>
</table>

Temperature: 10°C ... 40°C (50°F ... 104°F)
Relative humidity (non-condensing): 15–80%
Max. operating altitude: 3,000 m
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 Connecting the IMAGE1 S X-LINK
1. Plug the E-BOX for X-LINK into the IMAGE1 S.
2. Insert the connector from the flexible video uretero-riscope into the serial port on the E-BOX for X-LINK.
5.3 Connecting the C-MAC monitor

1. Insert the connector from the flexible uretero-renoscope into the serial port on the E-BOX. Note the arrow marker on the connector housing.

2. Insert the connecting cable from the E-BOX into the serial port on the C-MAC Monitor.

5.4 Performing the white balance

- The white balance must be performed again after replacing the endoscope.

1. Point the tip of the flexible video uretero-renoscope at a clean white surface, e.g., white gauze.
2. Make sure that the light source emits enough light to sufficiently illuminate the surface.
   - The monitor displays a completely white and well illuminated live image.
3. Press the White balance button.
   - The white balance is performed.
4. Check the monitor to see whether the white balance was successful.
5. Repeat the white balance if required.

5.5 Checking the function

Slowly move the deflection lever to check the deflection of the distal tip, see chapter Operating the deflection mechanism [p. 17].
6 Application

6.1 Operating the deflection mechanism

**WARNING**
Incorrect handling! Risk of injury!
If the deflection lever is moved with force or abruptly, the patient may be injured and the product may be damaged.

- Move the deflection lever with caution.

**WARNING**
Angled tip! Risk of injury!
The patient can be injured if the distal end of the product is angled when being introduced into the patient or removed.

- Place the distal end of the product in the straight position.
- Do not carry the product by the sheath. Do not pull, clamp or twist the sheath.

1. Take hold of the product.

6.1.1 Operating 091271-01, 091271-06

1. Move the deflection lever upward using the thumb to angle the distal tip downward.
2. Move the deflection lever downward using the thumb to angle the distal tip upward.
3. To place the distal tip in the straight position, move the deflection lever into the middle.

6.1.2 Operating 091279-01, 091279-06

1. Move the deflection lever upward using the thumb to angle the distal tip downward.
2. Move the deflection lever downward using the thumb to angle the distal tip upward.
3. To place the distal tip in the straight position, move the deflection lever into the middle.

6.2 Using the instrument channel

1. Attach an adaptor (e.g., 100010-10, 100040-10) to the first LUER-Lock connector.
2. Connect an irrigation tube to the second LUER-Lock connector.
7 Maintenance, servicing, repairs, and disposal

7.1 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 Electromagnetic compatibility

8.1 General information

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.

<table>
<thead>
<tr>
<th>Device</th>
<th>Item number</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMAGE1 S X-Link</td>
<td>TC301</td>
</tr>
<tr>
<td>C-MAC</td>
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<td>20290320</td>
</tr>
<tr>
<td>TELE PACK +</td>
<td>TP101</td>
</tr>
</tbody>
</table>

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.
9 Accessories and spare parts

9.1 Accessories

<table>
<thead>
<tr>
<th>Item</th>
<th>Order no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopic seal</td>
<td>100010-10</td>
</tr>
<tr>
<td>Tuohy Borst Adaptor</td>
<td>100040-10</td>
</tr>
</tbody>
</table>
10 Subsidiaries

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KARL STORZ Endoscopy Uretero-renoscope FLEX-XC1  
MTP003_EN_V1.1_02-2022_IFU_CE-MDR