KARL STORZ — ENDOSKOPE

en **Instructions for use**
Uretero-renoscope, ureteroscope, cystoscope-urethroscope

10-2020

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.
- Keep the instructions for use clearly visible next to the product.

1.2 Read the instructions for use of combinable products

If the instructions for use of combinable 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 combinable products carefully and follow all the safety notes and warnings.

1.3 Scope

These instructions for use are valid for the following products:

Product	Item number
Ureteroscope	27000K
	27001K
	27002K
	27011K
Uretero-renoscope	27000L
	27001L
	27002L
	27003L
	27011L
	27013L
Uretero-renoscope, pediatric	27002KP
Cystoscope-urethroscope, pediatric	27030KA/KB
Instrument inlet	27001G, 27001GF 27001GH
Insertion aid for guide wires	27001E

1.4 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 warning messages describe 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.

ATTENTION

ATTENTION

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

2 Normal use

2.1 Intended use

Ureteroscopes, uretero-renoscopes (27000K, 27001K, 27002K, 27011K, 27000L, 27001L, 27002L, 27003L, 27011L, 27013L)

Rigid/semirigid ureteroscopes/uretero-renoscopes (telescope) are used for endoscopic imaging of the ureter, the pyeloureteral junction, and the renal pelvis for the purposes of diagnosis and treatment.

Ureteroscopes/uretero-renoscopes with an integrated working channel allow for the use of auxiliary instruments such as forceps, scissors, stone baskets, etc., laser fibers and other lithotripters for the treatment of urinary stones, stenoses/strictures, and benign/malignant tumors. Ureteroscopes/uretero-renoscopes are designed for short-term use in invasive procedures through a body orifice.

Pediatric uretero-renoscopes (27002KP)

The uretero-renoscope/ureteroscope (telescope) or flex. uretero-renoscope is used for endoscopic imaging of the ureter and renal collecting system for the purposes of endourological diagnosis and treatment. The instruments are designed for short-term use in invasive procedures through a body orifice.

Pediatric cystoscope-urethroscope (27030KA/KB)

The telescope is used for endoscopic imaging and, if necessary, for creating a working or irrigation channel during endourological diagnosis and treatment. Compact cystoscopes are used for endoscopic imaging of the urethra and bladder for the purposes of diagnosis and treatment. The integrated working channel makes it possible to use flexible or semirigid auxiliary instruments such as forceps, stone baskets, etc., coagulation electrodes and laser fibers for lithotripsy or for the ablation of benign/malignant tissue. Telescopes/compact cystoscopes are designed for transient use in invasive procedures through a body orifice.

2.2 Indications

Ureteroscopes, uretero-renoscopes (27000K, 27001K, 27002K, 27011K, 27000L, 27001L, 27002L, 27003L, 27011L, 27013L)

The use of products for ureteroscopy/ureterorenoscopy is indicated if uretero(reno)scopy is indicated in the opinion of the responsible physician.

This includes:

- Further diagnostic measures in the event of conspicuous imaging and filling defects in the upper urinary tract shown in the imaging
- Pathological bladder-wash cytology without reference to bladder tumors or from the upper urinary tract
- Unclear hematuria (macro/microhematuria)
- Diagnosis and treatment of urinary stones in the ureter or renal collecting system
- Diagnosis and treatment of ureteral strictures or tumors – latrogenically introduced foreign material
- Narrow pyeloureteral junction
- Possibly the percutaneous antegrade treatment of kidney stones, tumors, and ureter outflow constrictions
- UUT (Upper Urinary Tract) tumors or UTUC (Upper Tract Urothelial Cancer)

- Nephrolithiasis of lower calyceal group
- Positive bladder-wash cytology from the upper urinary tract
- Tumors in the upper urinary tract

Indication for retrograde treatment of a transitional cell carcinoma:

- Impaired renal function/single kidney
- Bilateral tumor development
- Multiple comorbidities/limited life expectancy
- Tumor stages in which only palliation is possible

Pediatric uretero-renoscopes (27002KP)

The use of instruments for transurethral/percutaneous pediatric urology is indicated if an endourological procedure is indicated in the opinion of the responsible physician.

This includes, among other things:

Cystoscopy:

- Anomalies in the ureteral orifices
- Ureteroceles
- Vesicorenal reflux
- Enuresis
- Neurogenic micturition disorder/reflexive bladder

Ureterorenoscopy/PCNL:

- Nephrolithiasis/urolithiasis
- Ureteral strictures/stenoses
- Double ureter
- Upper ureteral calculi

Pediatric cystoscope-urethroscope (27030KA/KB)

The use of instruments for transurethral/percutaneous pediatric urology is indicated if an endourological procedure is indicated in the opinion of the responsible physician.

This includes, among other things:

Cystoscopy

- Anomalies in the ureteral orifices
- Ureteroceles
- Vesicorenal reflux
- Enuresis
- Neurogenic micturition disorder/reflexive bladder

Ureterorenoscopy/PCNL:

- Nephrolithiasis/urolithiasis
- Ureteral strictures/stenoses
- Double ureter
- Upper ureteral calculi

2.3 Contraindications

Ureteroscopes, uretero-renoscopes (27000K, 27001K, 27002K, 27011K, 27000L, 27001L, 27002L, 27003L, 27011L, 27013L)

The use of products for uretero(reno)scopy is contraindicated if, in the opinion of the responsible physician, the surgical method is contraindicated or the patient is not able to undergo surgery or anesthesia due to his or her general condition.

Uretero(reno)scopes and their accessories must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system.

The following contraindications also apply:

- Urinary tract infection
- Urosepsis
- Untreated/unresolved coagulation disorder
- Lithotomy position contraindicated
- Pregnancy

Pediatric uretero-renoscopes (27002KP)

The pediatric urological, transurethral, and percutaneous use of the instruments is contraindicated if, in the opinion of the responsible physician, the surgical method is contraindicated or the child is not able to undergo surgery or anesthesia due to his or her general condition. Instruments for pediatric urology must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system.

The following contraindications also apply:

- Acute urinary tract infection
- Unresolved coagulation disorders
- Neurogenic detrusor instability

Where children are concerned, the responsible physician must question the necessity and potential therapeutic consequences of any diagnostic or therapeutic endoscopic procedures.

Pediatric cystoscope-urethroscope (27030KA/KB)

The pediatric urological, transurethral, and percutaneous use of the instruments is contraindicated if, in the opinion of the responsible physician, the surgical method is contraindicated or the child is not able to undergo surgery or anesthesia due to his or her general condition. Instruments for pediatric urology must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system.

The following contraindications also apply:

- Acute urinary tract infection
- Unresolved coagulation disorders
- Neurogenic detrusor instability

Where children are concerned, the responsible physician must question the necessity and potential therapeutic consequences of any diagnostic or therapeutic endoscopic procedures.

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

According to the Medical Device Regulation (MDR), a “serious incident” includes incidents that directly or indirectly had, could have had, or could have any of the following consequences (MDR, Art. 2, No. 65 [1]):

- 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 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.

3.3 Correct handling

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 points before and after every use:

- Completeness
- Good working order
- Rough surfaces left inadvertently
- Sharp corners
- Burred edges
- Correct assembly of the components
- Functionality

▶ 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.

3.4 Damaged products

Damaged products can result in injury to patients, users, or third parties.

▶ Before each use, check all components of the product for damage.

▶ Do not use damaged products.

3.5 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.

3.6 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 light source output to a level that is just high enough to ensure optimal illumination of the operating area.
- Avoid contact with the distal end and light connections.

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.
- Set the light source output 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.

3.8 Appropriate combination of endoscope and fiber optic light cable

If the fiber 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 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 diameter.

3.9 Patient leakage current

Patient leakage currents from products may add up if powered products and powered endotherapy devices are used simultaneously. Excessively high leakage current levels may result in the patient becoming injured.

- Only use products of the same type together, particularly in the case of CF products.

3.10 Creutzfeldt-Jakob disease

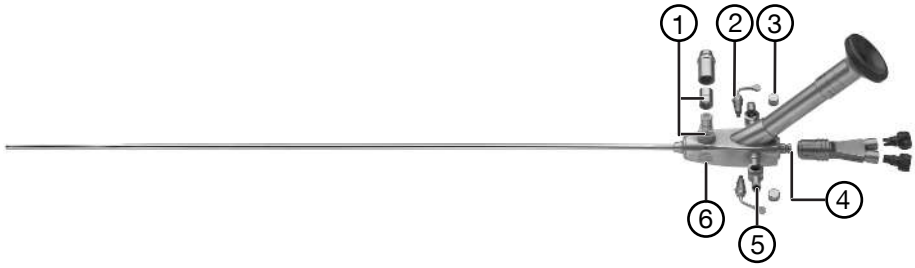
Products that come into contact with the central nervous system can become contaminated by organic residue containing prions. Prions lead to infection with Creutzfeldt-Jakob disease.

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

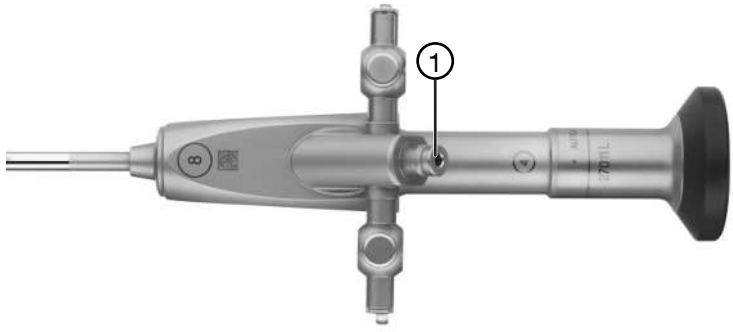
- Dispose of the product properly and do not continue to use it.

4 Product description

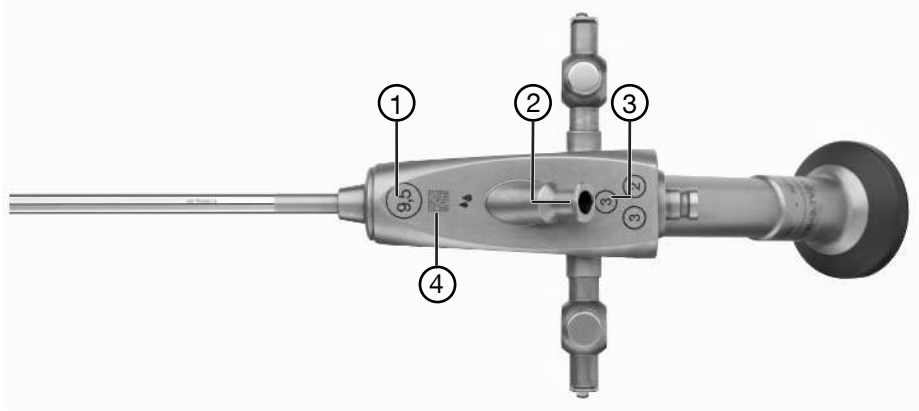
4.1 Product overview



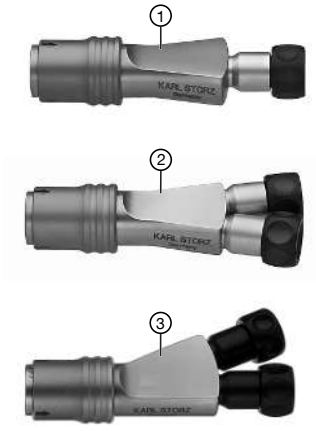
1	Light inlet socket	4	Mount for instrument inlet
2	Cock plug	5	Irrigation port
3	Spring cap	6	Symbol for light cable diameter



1	Mount for oblique instrument inlet (27011K/L, 27013L)

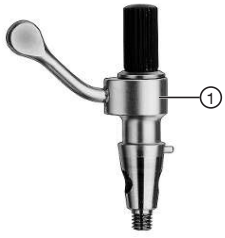


1	External dimension of the instrument	3	Maximum diameter of instruments
2	Irrigation port inflow (additional feature of 27003L)	4	Data matrix code for reading off the serial and article numbers



1 Instrument inlet (27001G)
2 Instrument inlet, 2 channels (27001GF)
3 Instrument inlet, 2 channels (27001GH)

1 Cleaning adaptor (27001RA)



1 Flow control stopcock (27504)

4.2 Possible combinations

Possible combinations: endoscope – instrument inlet

Uretero-renoscopes	Instrument inlet	Insertion aid
27000K 27000L 27001K 27001L 27002K 27002L 27003L 27011K 27011L 27013L 27030KA 27030KB	27001G 27001GF 27001GH	27001E (only in combination with 27001G)
27002KP	27001G	27001E

Possible combinations: endoscope – forceps, scissors, instruments

Endoscope	Forceps, scissors, instrument
27000K 27000L 27001K 27001L 27002K 27002L	27424F 27424P 27424R 27424Z 27424U Laser fiber Lithotripsy probe
27003L 27002KP	27023FM Laser fiber
27002K 27002L	27425F 27425P 27425R 27425Z 27425U Laser fiber Lithotripsy probe
27030KA	27071TJ 27071ZJ 27030EL 27770AA 27770A

Endoscope	Forceps, scissors, instrument
	27030M 27030N
27030KB	27095F 27095P 27095Z 27030M 27030N 27030EL 27770AA 27770A 27770B 27772AA 27772A

Possible combinations: endoscope – stone basket

Endoscope	Stone basket
27000K 27000L 27001K 27001L 27002K 27002L 27003L 27011K 27011L 27013L 27002KP	27023LD 27023LF 27023TD 27023TF 27023KF
27002K 27002L	27023VK

Possible combinations: endoscope – cytology brush

Endoscope	Cytology brush
27000K	27023Y
27000L	
27001K	
27001L	
27002K	
27002L	
27003L	
27011K	
27011L	
27013L	
27002KP	

Possible combinations: light connection – fiber optic light cable

In combination with the product, light cables with a fiber diameter of 2.0 – 2.5 mm are recommended. The circle symbol on the product and the circle symbol on the light cable must match each other.

Circle symbols	Diameter of light cable
	4.8 – 5.0 mm
	3.0 – 3.5 mm
	2.0 – 2.5 mm

Combination: working channel – irrigation

Irrigation tubes can be connected via the LUER lock connection.

Possible combinations: eyepiece – camera head

Camera heads with a standardized KARL STORZ eyepiece connection can be connected to the eyepiece.

4.3 Ambient conditions

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

4.4 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Consult instructions for use
	Medical device
	Unique Device Identifier
	Article no.
	Batch code
	Serial number
	Number of products in the product packaging
	Unsterile
	Fragile, handle with care
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE mark. The CE mark is a label required for certain marketable industrial products in accordance with EU law. It consists of the CE logo and, where applicable, the four-figure identification number of the responsible testing center (when the product belongs to a certain risk category).

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 evidence of shipping 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

1. Hold the instrument inlet on the two flat sides and push it onto the mount until the instrument inlet clicks into place.

2. If the instrument inlet does not click into place, push back the sleeve of the instrument inlet.
3. Insert the cock plug into the irrigation ports.

4. Place the spring cap on the thread of the cock plugs.
5. Tighten the spring cap slightly.
6. Fit the plug-in base (495F) onto the light inlet socket.
7. Screw the screw base (495G) onto the light inlet socket.

6 Disassembly

6.1 Disassembling the product

1. Unscrew the screw base from the light inlet socket.
2. Remove the plug-in base from the light inlet socket.
3. Unscrew the spring cap from the cock plug.
4. Remove the cock plug from the irrigation ports.

5. Push back the sleeve of the instrument inlet.
6. Remove the instrument inlet from the mount.

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.
Fiber optic light cable, length 230 mm, diameter 2.5 cm	495NTA

8.2 Spare parts

Item	Order no.
Plug-in base, 9 mm in diameter, for Wolf fiberoptic light cables	495F
Screw base for KARL STORZ fiberoptic light cables and Olympus Corporation	495G
Seal for instrument inlets, pack of 10, single use recommended	27550N
Flow control stopcock	27504
Spring cap	6985691
Cock plug	8458190
Cleaning adaptor for instrument inlets	27001RA

9 Subsidiaries

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