

STORZ

KARL STORZ—ENDOSKOPE

en **Instructions for use**
HF cable



11-2023

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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:

Monopolar HF cables

Product name	Item number
Unipolar High-Frequency Cable, 300 cm	277
Unipolar High-Frequency Cable, 300 cm	277A
Unipolar High-Frequency Cable, 300 cm	277KA
Unipolar High-Frequency Cable, 300 cm	277KB
Unipolar High-Frequency Cable, 300 cm	277KE
Unipolar High-Frequency Cable, 300 cm	279
Unipolar High-Frequency Cable, 300 cm	279KA
Unipolar High-Frequency Cable, 300 cm	279KB
Unipolar High-Frequency Cable, 300 cm	279KE
Unipolar High-Frequency Cable, 300 cm	26002M
Unipolar High-Frequency Cable, 300 cm	26004M
Unipolar High-Frequency Cable, 300 cm	26005M
Unipolar High-Frequency Cable, 300 cm	26006M
Unipolar High-Frequency Cable, 500 cm	277AL
Unipolar High-Frequency Cable, 500 cm	277KBL

Product name	Item number
Unipolar High-Frequency Cable, 500 cm	277KEL
Unipolar High-Frequency Cable, 500 cm	277L
Unipolar High-Frequency Cable, 500 cm	279KBL
Unipolar High-Frequency Cable, 500 cm	26002ML
Unipolar High-Frequency Cable, 500 cm	26004ML
Unipolar High-Frequency Cable, 500 cm	26005ML
Unipolar High-Frequency Cable, 500 cm	26006ML
Unipolar High-Frequency Cable, 600 cm	26002MR

Bipolar HF cables

Product name	Item number
Bipolar High-Frequency Cable, 300 cm	26176LE
Bipolar High-Frequency Cable, 300 cm	26176LM
Bipolar High-Frequency Cable, 300 cm	26176LV
Bipolar High-Frequency Cable, 300 cm	26176LW
Bipolar High-Frequency Cable, 300 cm	847000E
Bipolar High-Frequency Cable, 300 cm	847000M
Bipolar High-Frequency Cable, 300 cm	847000V
Bipolar High-Frequency Cable, 300 cm	847000W
Bipolar High-Frequency Cable, 450 cm	847002V
Bipolar High-Frequency Cable, 500 cm	26176LEL
Bipolar High-Frequency Cable, 500 cm	26176LML
Bipolar High-Frequency Cable, 500 cm	26176LVL
Bipolar High-Frequency Cable, 600 cm	26176LER

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 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.

1.5 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

High-frequency cables

High-frequency cables are intended to connect application parts to high-frequency generators. High-frequency cables do not have body contact.

2.2 Indications

The high-frequency generator with the corresponding accessories is suitable for all application parts that require the energies provided in the chapter "Technical data" of the corresponding instructions for use for successful performance.

2.3 Contraindications

The high-frequency generator with the corresponding accessories is not used in direct contact with the patient, but provides energy and power for HF application parts. Use with the corresponding application parts is contraindicated if the use of these application parts is contraindicated.

The unit is not suitable for application parts that require continuous activation of the high-frequency generator.

2.4 Clinical benefits

Unlike mechanical transection of tissue, electrocautery uses a short, intense electric current that transects or vaporizes tissue, depending on the duration of application. Electrocautery in surgery is now widely used in virtually all routine operations, particularly as a viable, rapid, and essentially harmless means of obliterating small and medium-sized blood vessels for the purpose of intraoperative hemostasis.

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.

- ▶ 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 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 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*.
- ▶ 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 Peak voltage output

In combination with HF devices, this product must only be exposed to a specific, recurring maximum peak voltage output. If the maximum permissible peak voltage output is exceeded, the product may be damaged. Damaged products can result in injury to patients, users, and third parties.

- ▶ Select the generator setting so that the maximum permissible peak voltage output is not exceeded; see *Technical data*.

3.5 Electromagnetic interference

Electrosurgical systems create an electromagnetic field. This can impair or damage other electronic devices and active implants (such as pacemakers).

- ▶ Observe the information on electromagnetic compatibility of the electrosurgical generator being used.
- ▶ In case of uncertainties, seek expert advice from KARL STORZ.

3.6 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



Monopolar HF cables



Bipolar HF cables

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.

Components that are connected to an instrument and linked to an HF generator via an HF cable form a single HF applied part.

Combinations of monopolar HF cables with HF instruments and HF generators

HF instrument	HF generator		
	AUTOCON III 400 AUTOCON III 300 AUTOCON II 200 AUTOCON II 80 AUTOCON (series 50, 200, 350)	AUTOCON III 400 AUTOCON III 300 AUTOCON II 400 SCB (series 112, 116)	AUTOCON III 400 AUTOCON III 300
Monopolar Resection Instruments	277KE 277KEL 277 A 277AL	277KB 277KBL	277 277L
Monopolar Resection Instruments	279KA 279KE	279KB 279KBL	279 279L
CLICKLINE Instruments	26005M 26005ML 26004M 26004ML	26006M 26006ML	26002M 26002ML

Combinations of bipolar HF cables with HF instruments and HF generators

HF instrument	HF generator		
	AUTOCON III 400 AUTOCON III 300 AUTOCON II 400 AUTOCON II 200 AUTOCON II 80	AUTOCON III 400 AUTOCON III 300 AUTOCON II 400	Two 4 mm pins spaced 22 mm apart
ROBI	26176LV 26176LVL 26176LE 26176LEL 26176LM 26176LML	–	26176LW
ENT Instruments	847002V	–	–
Coagulating Forceps	847000V	847000E 847000V 847000W	–

4.3 Technical data

Monopolar HF cables (279, 279KA, 279KB, 279KE)

Designation	Value
HF application	Monopolar
Max. peak voltage output	3.0 kVp

Monopolar HF cables

Designation	Value
HF application	Monopolar
Max. peak voltage output	4.5 kVp

Bipolar HF cables

Designation	Value
HF application	Bipolar
Max. peak voltage output	1.5 kVp

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

Symbol	Meaning
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	Unsterile
	Keep away from sunlight
	Keep dry
	Temperature limit
	Humidity limit
Rx only	Federal (USA) law restricts this device to sale by or on the order of a physician.
CE	CE marking 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. The EU directives 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 and storage conditions	
Temperature	-29°C ... +50°C (-20°F ... +122°F)
Relative humidity (non-condensing)	5–85%
Operating conditions	
Temperature	10°C ... 35°C (50°F ... 95°F)
Relative humidity (non-condensing)	30–75%

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 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.

6 Application

6.1 Using the product

⚠ WARNING**Insufficient electrical contact! Risk of injury!**

Poor connections can lead to high voltages, voltage flashovers, and malfunctions. This may cause injuries to patients, users, and third parties.

- ▶ Ensure that the contacts and connection insulation are in perfect condition.
 - ▶ Connect the connection correctly. There must not be any visible open electrical contacts.
 - ▶ Observe the locking systems and markings on the connection.
1. Route the HF cables so that contact with the patient or other cables is avoided.
 2. Make sure that equipment carts and similar equipment cannot roll over and squash the HF cables.
- ① To ensure correct operation, the connecting cable must not exceed 450 cm in length in the case of bipolar applications in autostart mode.

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

For disposal, the following measures are necessary:

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

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