KARL STORZ — ENDOSKOPE

en

Instructions for use
DRILLCUT-X ARTHRO Shaver Handpiece

08-2024

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:

Shaver handpieces

Product name	Item number
DRILLCUT-X ARTHRO Shaver Handpiece	28200DX

Adapters

Product name	Item number
Adaptor	28200DXA

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 use

Shaver handpieces

Shaver handpieces are intended to hold and to drive rotary and oscillating instruments by mechanically transmitting and converting speeds and torques as well as directions of rotation during shaver application. Shaver handpieces are non-invasive and meant for transient use.

Adapters

Adapters are intended for electrical signal transmission. Adapters do not have body contact.

2.2 Indications

Shaver handpieces

The medical devices are suitable for use in minimally invasive investigations and treatments of a joint such as knee joints, shoulder joints, hip joints, small and medium joints (such as elbows, wrists, and ankles).

Adapters

Adapters are used for electrical signal transmission. They do not depend on special indications.

2.3 Contraindications

Shaver handpieces

The medical devices must not be used for interventions in direct contact with the CNS (central nervous system) and central circulatory system. In addition, there are no contraindications directly associated with the product for the use of medical devices.

Adapters

Use is contraindicated if, in the opinion of the responsible physician, the device is not compatible with successful completion of the planned procedure due to its technical design. The accessories must only be used with the intended devices. In general, medical devices must not be used on patients who are not part of the defined patient group, or if the operation itself is contraindicated.

2.4 Clinical benefits

Shaver handpieces

The products permit the performance of arthroscopic interventions on joints such as knee joints, shoulder joints, hip joints, small and medium joints (such as elbows, wrists, and ankles).

Adapters

Adapters are accessories for medical devices. They do not have own clinical benefit for the patient, only in combination with the devices they are connected to.

2.5 Residual risks

Shaver handpieces

- Tissue traumatization related acute and chronic complications
- Contamination that could lead to infections

Adapters

No residual risks are known when instructions for use are followed.

2.6 Target user populations

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

2.7 Patient population

Shaver handpieces

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

Adapters

No restriction of the patient population.

The application of the products is not limited to a certain patient profile (gender, age, weight etc.). However, the products are available in different sizes / diameters and are chosen by the responsible medical specialist in line with the anatomical structures of the patient.

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

For detailed inspection criteria, see section *Inspecting the product*.

- Do not continue to use damaged products.
- Dispose of the product properly; see *Disposing of the product*.

3.3 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.

3.4 Combination with other components

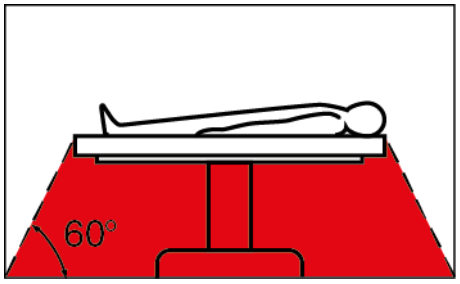
The use of unauthorized devices and components may result in injuries.

- Ensure that any additional devices connected to electrical medical devices comply with the relevant IEC or ISO standards.
- Ensure that all configurations comply with the requirements for medical electrical systems.

3.5 Risk of explosion and fire

The product can generate sparks, which cause combustible or flammable gases and liquids to ignite or explode. This may cause injuries to patients, users, and third parties.

- When using explosive narcotic gases: Operate the product outside of the hazard zone.



- Do not use the product in the presence of flammable anesthetics.
- The product must not be operated in oxygenated environments.
- Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

3.6 Dangers from electrical current

In the case of electrical products, individual components or the product itself may be live. Live parts can cause electric shocks in the event of contact and injure patients, users, and third parties.

- Do not open the product.
- Have servicing carried out by KARL STORZ or a company authorized by KARL STORZ.
- Always pull out the mains plug before carrying out any cleaning and maintenance work.

3.7 Electromagnetic interference

Medical electrical devices are subject to special precautions regarding electromagnetic compatibility. If other devices (e.g., MRT, CT, diathermy, electrocautery, or RFID) emit electromagnetic radiation, the product's functionality may be impaired. High-frequency (HF) communication equipment can affect electrical medical devices and impair their performance.

- During installation and operation of the product, please take note of the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility*.

3.8 Failure of products

The product may fail during use.

- Have a replacement product ready for each application or plan for an alternative surgical technique.

3.9 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.

3.10 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.

4 Product description

4.1 Product overview

DRILLCUT-X ARTHRO Shaver Handpiece (28200DX)

1	Tilt lever	5	Handpiece
2	Buttons	6	Valve body
3	Connecting piece	7	Valve lock
4	Connecting cable	8	Locating sleeve

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.

The product can be combined with the following components:

Shaver Handpiece	Motor Control Unit	Shaver Blade
28200DX	UM600	28205ABS, 28205ACS 28205ADS, 28205AKS 28205BCS, 28205CBS 28205CCS, 28205CDS 28205CKS, 28205DBS 28205DCS, 28205DDS 28205DKS, 28205EGS 28205EHS, 28205FCS 28205FDS, 28205GDS 28205GES, 28205HCS 28205HDS, 28205HES 28205MDS, 28205MKS 28205NDS, 28205NKS 28206AAS, 28206ABS 28206CAS, 28206CBS 28206DAS, 28206DBS 28206FAS, 28206FBS 28208BKS, 28208DCS 28208EHS, 28208IDS 28205AB, 28205AC 28205AD, 28205AK 28205BC, 28205CC 28205CK, 28205DB 28205DC, 28205DD 28205DK, 28205FC 28205GE, 28205HC 28205HD, 28205HE 28205MK, 28205ND 28205NK, 28206DA 28206DB

4.3 Technical data

Description	Value
Dimensions (L x H x W)	152 × 30 × 43 mm
Weight with cable	570 g
Average life cycle	300 reprocessing cycles
Minimum speed, oscillation mode	500 rpm

Description	Value
Maximum speed, oscillation mode	5,000 rpm
Minimum speed, rotation mode	1,000 rpm
Maximum speed, rotation mode	8,000 rpm

The instructions for use for the motor control unit contain more detailed technical data for using the shaver handpieces in combination with other medical devices.

4.4 Symbols on the packaging

Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	Unsterile
	Keep dry
	Temperature limit
	Humidity limit

Symbol	Meaning
	Air pressure limit
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU regulations. A code number after the CE mark indicates the responsible notified body. The EU regulations relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

4.5 Ambient conditions

For 28200DX

Transport and storage conditions	
Temperature	-18°C … +60°C (-0.4°F … +140°F)
Relative humidity (non-condensing)	5–85%
Air pressure	600–1,080 hPa

Operating conditions	
Temperature	10°C … 30°C (50°F … 86°F)
Relative humidity (non-condensing)	30–75%
Air pressure	600–1,080 hPa

For 28200DXA

There are no special transport, storage, or operating conditions for these products.

5 Preparation

5.1 Unpacking the product

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

5.3 Testing the product

1. Inspect devices for visible contamination. Do not use contaminated devices.
2. Inspect devices for the following characteristics:

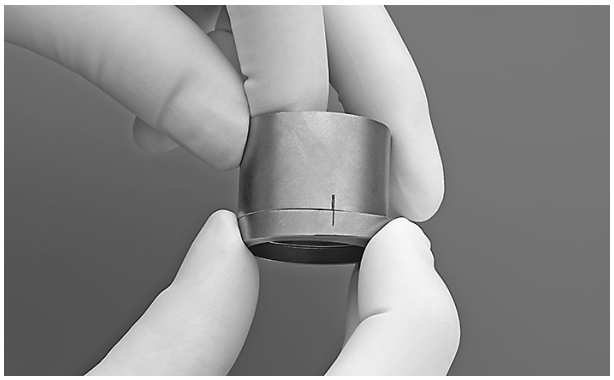
– Good working order
– Functionality
– Correct assembly of the components
– Completeness

▶ Inspect the product for damage, e.g.,

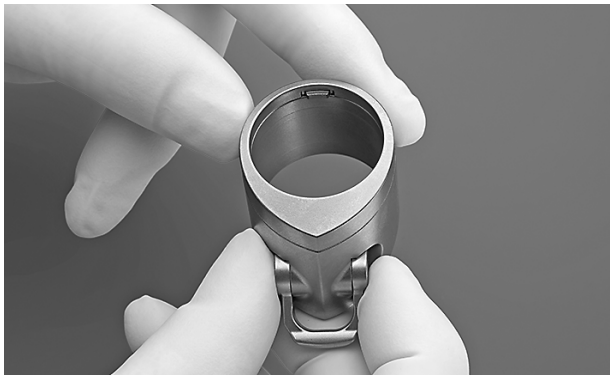
– Rough surfaces
– Sharp corners
– Burred edges
– Protruding parts

5.4 Assembling the product

1. Attach the valve lock to the valve body.
   Make sure that the line on the valve lock lines up with the line on the valve body.

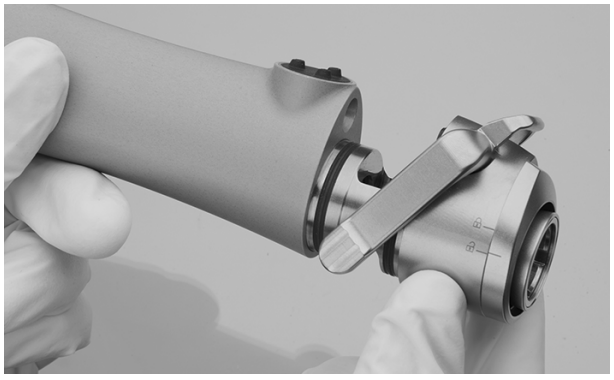


2. Turn the valve lock until it noticeably clicks into place with the locking ball.
   ⇨ The valve lock will now be sitting perfectly on the valve body.



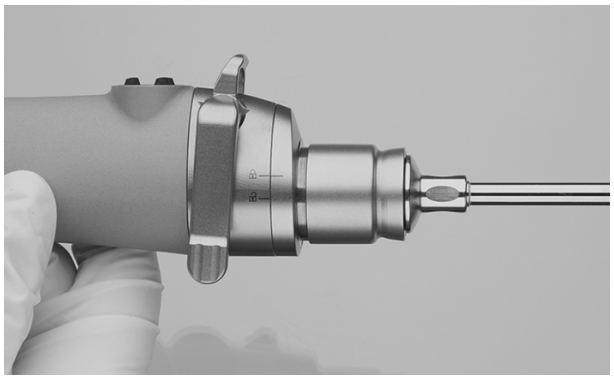
3. Turn the valve lock counter-clockwise until the line on the valve lock lever lines up with the open padlock symbol on the valve body.

4. Push the valve assembly onto the handpiece in the proximal direction as far as it will go.



5. Turn the valve lock clockwise until it sits perfectly on the valve body and the line on the valve lock lever lines up with the closed padlock symbol on the valve body.

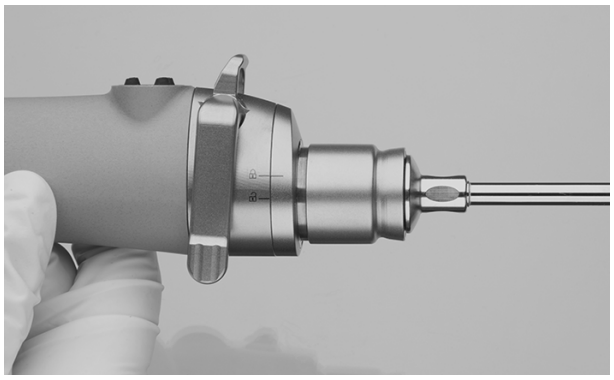
⇨ The valve assembly is now secured to the handpiece.



5.5 Assembling the blade on the product

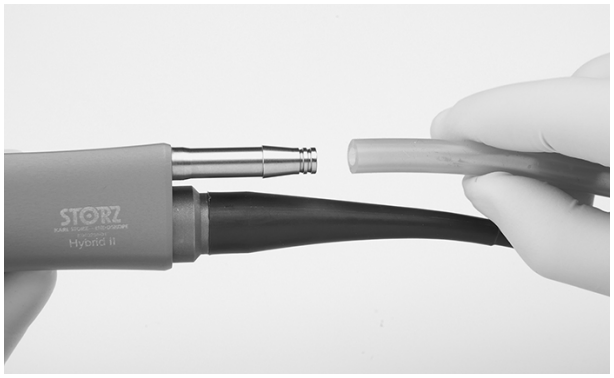
1. Pull the locating sleeve on the handpiece back in the proximal direction and push the blade into the handpiece as far as it will go.
2. Release the locating sleeve.

⇨ The blade is now secured to the handpiece.



5.6 Connecting the product

1. Connect the suction tube to the product connecting piece.



2. Connect the suction tube to a suction pump or wall suction.
3. Connect the handpiece connecting cable to the adaptor. Ensure that the red dot on the connecting cable is aligned with the red dot on the adaptor.

4. Connect the adaptor to the connection socket on the motor system. Ensure that the red dot on the connecting cable is aligned with the red dot on the connection socket.

6 Application

6.1 Using the product

⚠ CAUTION

Overheating due to insufficient suction! Risk of burns and product damage!

Inadequate suction can result in a contaminated or blocked product, or cause jerky movements. This will result in increased heat generation, endangering users and patients.

- When using rotating instruments, ensure that there is sufficient suction.

⚠ CAUTION

Overheating due to continuous operation! Risk of burns and product damage!

Continuous operation will cause the handpiece to heat up. This may endanger users and patients and result in damage to the product.

- Operate the product in intermittent mode: 5 minutes on, 5 minutes off, with maximum continuous operating time: 9 cycles of intermittent operation.
- Follow the instructions for use provided with the control unit.

NOTICE

Overheating due to leaking irrigation fluid! Risk of burns and product damage!

If the valve assembly is not mounted correctly on the front end of the handpiece, irrigation fluid may leak out. Sufficient suction is no longer guaranteed. This will result in increased heat generation, endangering users and patients.

- Before each use, make sure that the valve assembly is correctly mounted.

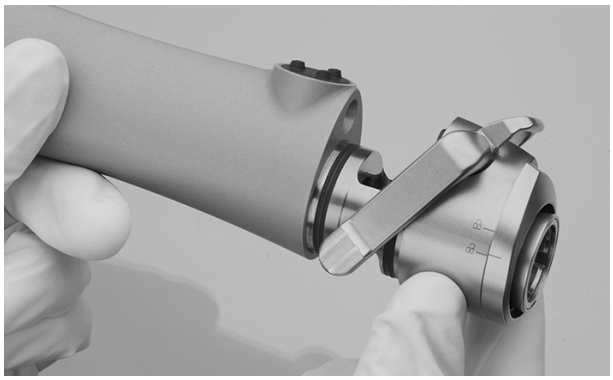
1. Push the tilt lever back to reduce the suction power.
2. Push the tilt lever forward to increase the suction power.
3. While the handpiece is not running, press the right button to switch to oscillation mode.
4. While the handpiece is running, press the right button to increase the speed.
5. While the handpiece is not running, press the left button to change the rotation from forward to reverse.
6. While the handpiece is running, press the left button to reduce the speed.
7. Press the middle button to start or stop the handpiece.
8. In the event of a blockage in the shaver attachment or the valve, remove the shaver attachment.
9. Flush the shaver attachment or valve body with a syringe.
10. To prevent blockages, activate the suction function, open the cutting opening, and flush distilled water through the shaver attachment after use.

7 Disassembly

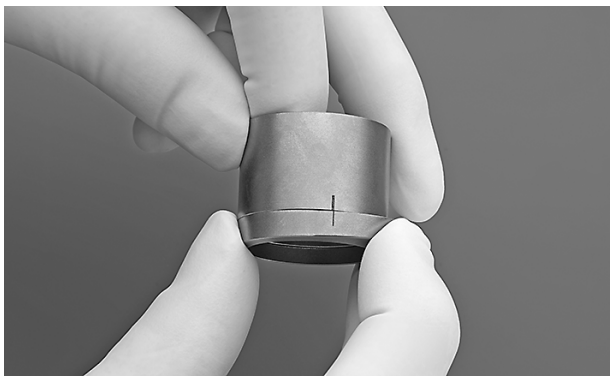
7.1 Disassembling the product

1. Turn the valve lock counter-clockwise until the line on the valve lock lever lines up with the open padlock symbol on the valve body.

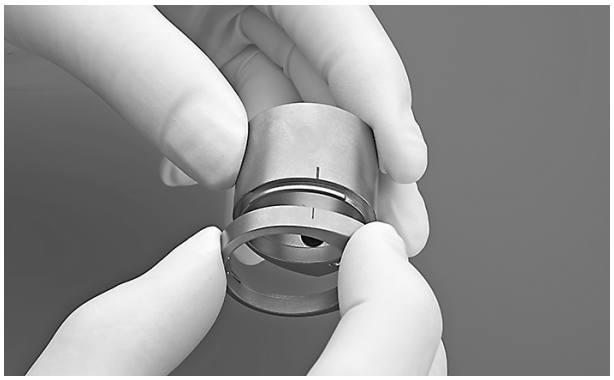
2. Remove the valve assembly from the handpiece in the distal direction.



3. Turn the valve lock counter-clockwise until the line on the valve lock lines up with the line on the valve body.

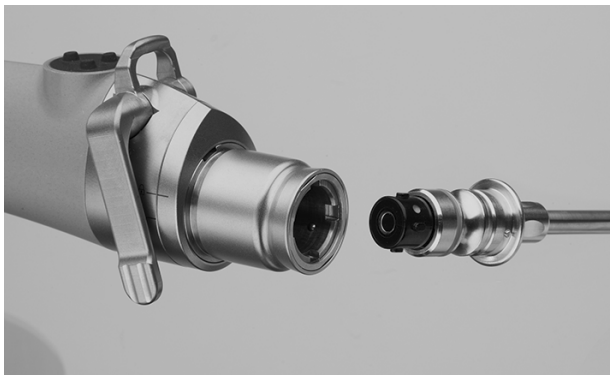


4. Remove the valve lock from the valve body.



7.2 Removing the blade from the product

1. Pull the locating sleeve on the handpiece back in the proximal direction and pull the blade out of the handpiece.
2. Release the locating sleeve.

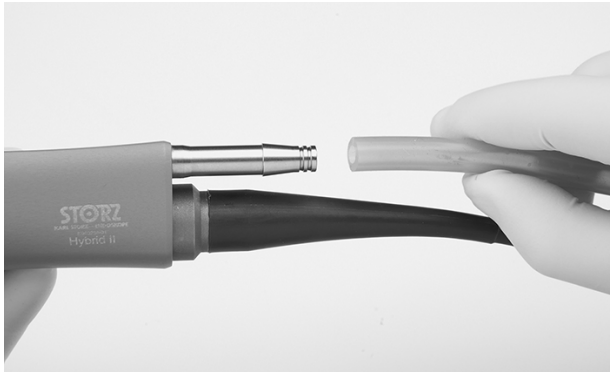


7.3 Disconnecting connections

1. Disconnect the adaptor from the connection socket on the motor system.

2. Disconnect the handpiece connecting cable from the adaptor.
3. Disconnect the suction tube from the suction pump or wall suction.

4. Remove the suction tube from the product connecting piece.



8 Maintenance, servicing, repairs, and disposal

8.1 Safety inspection in accordance with IEC 62353

⚠ WARNING

Risk of injury due to product degradation!

Patients, users and third parties may be injured as a result of product and accessory degradation.

- ▶ Shut down the product.
- ▶ Have the deficiencies repaired by persons authorized by KARL STORZ.

Regardless of the national accident prevention regulations and testing intervals for medical devices, for this device safety checks must be performed as repeat inspections according to IEC 62353 and recorded by a qualified electrician at least once a year. Detailed specifications regarding the scope and execution of the safety inspection can be found in the service manual.

8.2 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.

8.3 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.

9 Accessories and spare parts

9.1 Accessories

Item	Order no.
Valve Body without Valve Lock 28200DX	28200DA
Adaptor	28200DXA

10 Electromagnetic compatibility

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.

Device	Item number
UNIDRIVE Select	UM600

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.

The product described is suitable for use connected to a control unit in close proximity to an active HF electrosurgical device in professional healthcare facility environments. Professional healthcare facilities include physician offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birth centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgical rooms, outside the HF-shielded room of an ME system for MRT).

The emission characteristics of this product make it suitable for use in industrial areas as well as in hospitals (CISPR 11 Class A) and other professional healthcare environments. If it is used in a residential environment (for which CISPR 11 Class B is normally required), the product may not offer sufficient protection for radio transmission operation. The user might need to take mitigation measures, such as relocating or re-orienting the product.

11 Subsidiaries

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