

STORZ

KARL STORZ—ENDOSKOPE

en **Instructions for use**
Tubing sets for irrigation and suction



ATTENTION:

USA CUSTOMERS: Please note the following content is not applicable to U.S. customers. U.S. instructions can be found here:

<https://www.karlstorz.com/>

CANADIAN CUSTOMERS: For the applicable instructions for use for Canadian customers, please access the instructions:

<https://www.karlstorz.com/>



12-2025

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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:

Tubing sets for irrigation

Product name	Item number
Tubing Set, irrigation, FC	UP007
Tubing Set, irrigation, PC	UP008

Tubing sets for suction

Product name	Item number
Tubing Set, suction, DS	UP009

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 the case of a single step:

► Step 1

Actions in safety notes:

▷ Step 1

▷ Step 2

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

Tubing sets for irrigation

Tubing sets for irrigation are intended for transfer (carriage) of irrigation fluids to the irrigation instruments.

Tubing sets for irrigation are non-invasive and meant for short term use.

Tubing sets for suction

Tubing sets for suction are intended for transfer of fluids, tissue/particles and gases from the patient to the collection system.

Tubing sets for suction do not have body contact.

2.2 Indications

UP007

The medical devices are suitable for endoscopic procedures where irrigation functions are required. This includes procedures in the following medical fields:

- Urology
- Gynecology
- Surgery (thoracoscopy, laparoscopy, and proctology)

UP008

The medical devices are suitable for endoscopic procedures where irrigation functions are required. This includes procedures in the following medical fields:

- Urology
- Gynecology
- Arthroscopy
- Spinal surgery

UP009

The medical devices are suitable for endoscopic procedures where suction functions are required. This includes procedures in the following medical fields:

- Urology
- Gynecology
- Arthroscopy

2.3 Contraindications

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

Furthermore, there are no contraindications for the use of the medical devices directly associated with the product.

2.4 Clinical benefits

The products are involved in the delivery of fluid to and from the patient at a set pressure and/or flow rate to allow the performance of the following procedures:

- Hysteroscopy: the fluid delivered by the pump distends the uterine cavity to permit the visualization and the performance of endoscopic procedures in the uterine cavity. The pump can also be used for the suction of fluid from the uterine cavity when used in combination with the IBS (Intrauterine Bigatti Shaver).
- Arthroscopy: the irrigation fluid delivered by the pump distends the joint capsule to permit the visualization and the performance of arthroscopic procedures.
- Urology: the fluid delivered by the pump distends the urinary tract to permit the visualization and the performance of endoscopic procedures in the urinary tract. The pump can be also used for the suction of fluid from the urinary tract when used in combination with Calcuson or during resection.
- Surgery (Laparoscopy, Thoracoscopy, Proctology and Spine): the fluid delivered by the pump can be used to flush blood and debris from the operating field.
- ENT / Neurology: the fluid delivered by the pump can be used to flush the lens of the endoscope.

(Depending on the pumps or programs on the pumps used not all products are involved in all procedures)

2.5 Residual risks

No residual risks directly related to the product could be identified.

The following risks have been identified in clinical literature to be related to the use of irrigation fluid for distension of body cavities:

- Gas embolism
- Fluid overload / extravasation
- Hypotensive bradycardic events in arthroscopy
- Hypothermia in arthroscopy
- Intolerable pain and increased hypertension in hysteroscopy
- Perirenal hematoma

The side-effects described above relate to the use of irrigation fluid for distension of body cavities. No reliable data shows a difference in side-effects relating to the use of pumps compared to gravity induced irrigation. Therefore, the side-effects are considered acceptable with regards to the use of pumps.

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.

- ▷ Carefully read and observe all warnings and safety notes.
- ▷ Follow the instructions.

3.1 Serious incidents

A 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following:

- The death of a patient, user or other person,
 - The temporary or permanent serious deterioration of a patient's, user's or other person's state of health,
 - A serious public health threat.
- ▶ 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 chapter *Test the product* [p. 13].

- ▶ Do not continue to use damaged products.
- ▶ Dispose of the product properly, see chapter *Disposing of the product* [p. 22].

3.3 Failure of devices

A crushed pump tube will cause the safety system to stop the pump.

Pressure measuring membranes that are damaged or that have been exposed to excessively high pressures can lead to accidental device stoppages.

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

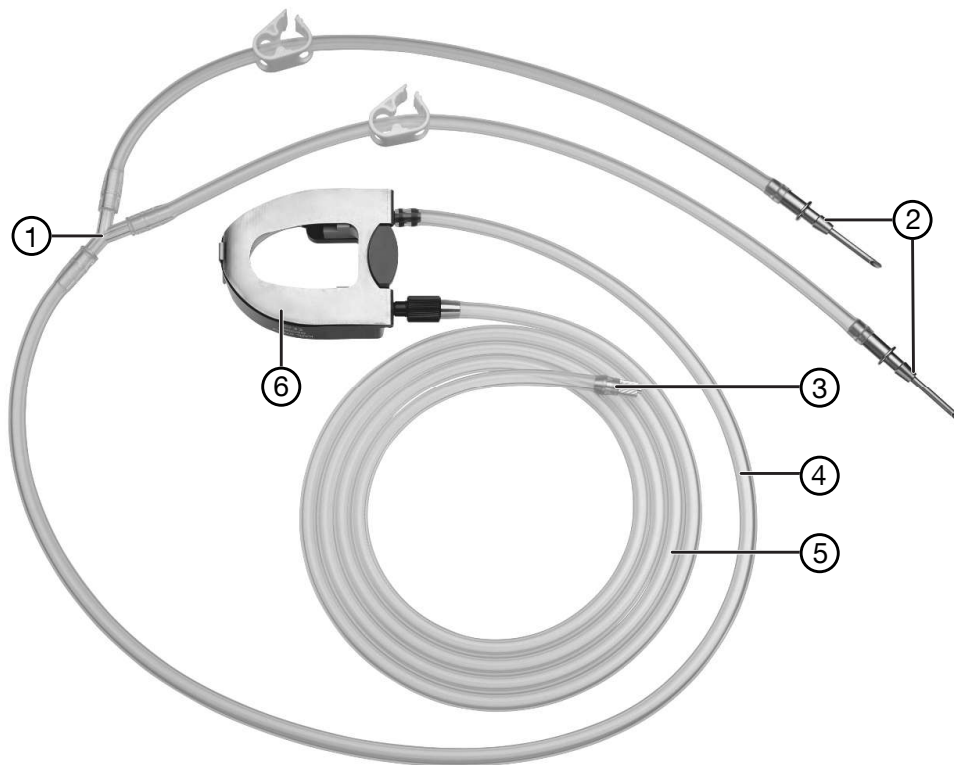
3.4 Non-sterile product

The product is not sterile when delivered. The use of non-reprocessed 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.

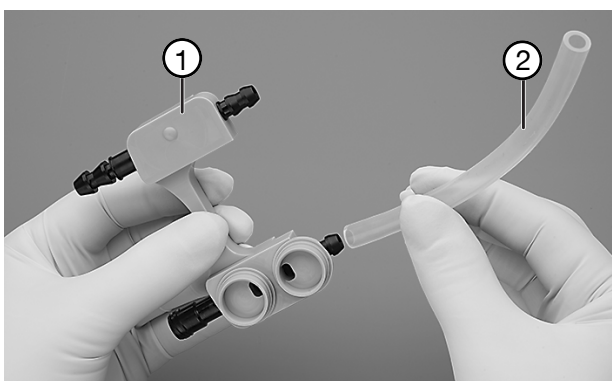
4 Product description

4.1 Product overview



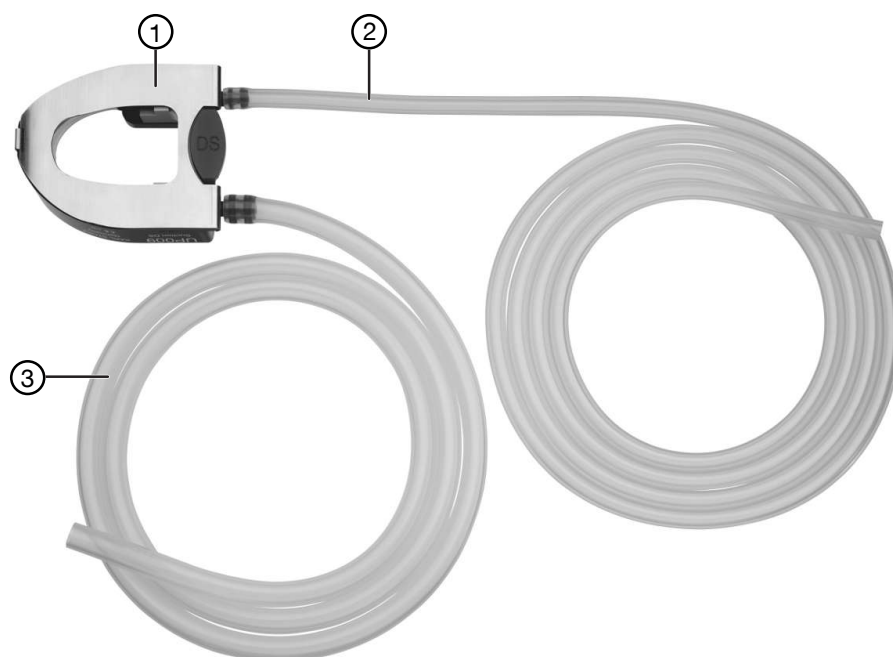
Tubing Set (UP007 and UP008)

- | | |
|-----------------------|---|
| 1 T-connector | 4 Irrigation bottle tube |
| 2 Metal mandrel | 5 Patient tube |
| 3 LUER-Lock connector | 6 Metal housing with inner part and cassette body |



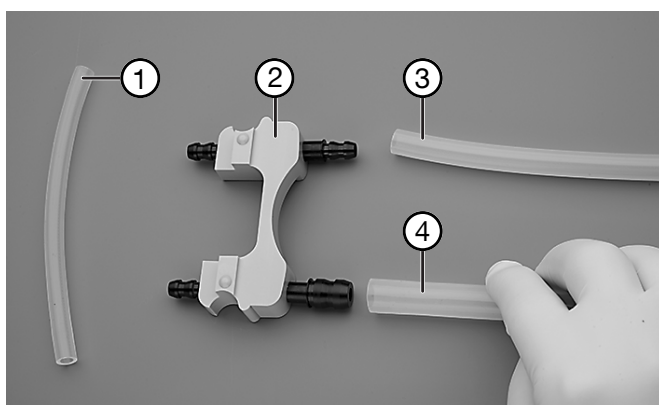
Components in the inner part

- | | |
|-----------------|-------------|
| 1 Cassette body | 2 Pump tube |
|-----------------|-------------|



Tubing Set (UP009)

- | | | | |
|---|---|---|--------------|
| 1 | Metal housing with inner part and cassette body | 3 | Patient tube |
| 2 | Suction tube | | |



Components in the inner part

- | | | | |
|---|---------------|---|-----------------|
| 1 | Pump tube | 3 | Irrigation tube |
| 2 | Cassette body | 4 | Patient tube |

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:

Tubing Set	Pump		
	UP210	UP220	26331120-1
UP007	X	X	X
UP008	X	X	X
UP009	X	X	–

4.3 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.)
	Non-sterile
	Keep away from sunlight
	Keep dry
	Temperature limit

Symbol	Meaning
	Humidity limit
	Air pressure limit
	Do not use if package is damaged.
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 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.

4.4 Ambient conditions

Transport conditions	
There are no special transport conditions for these products.	
Storage conditions	
Temperature	-10°C ... 60°C (14°F ... 140°F)
Relative humidity (non-condensing)	5–95%
Air pressure	500–1,080 hPa
Operating conditions	
There are no special 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 Test the product

- ① The product must be checked using the leakage tester (13242XL) before use. The max. pressure for the tubing sets (UP007 and UP008) is 100 mmHg.

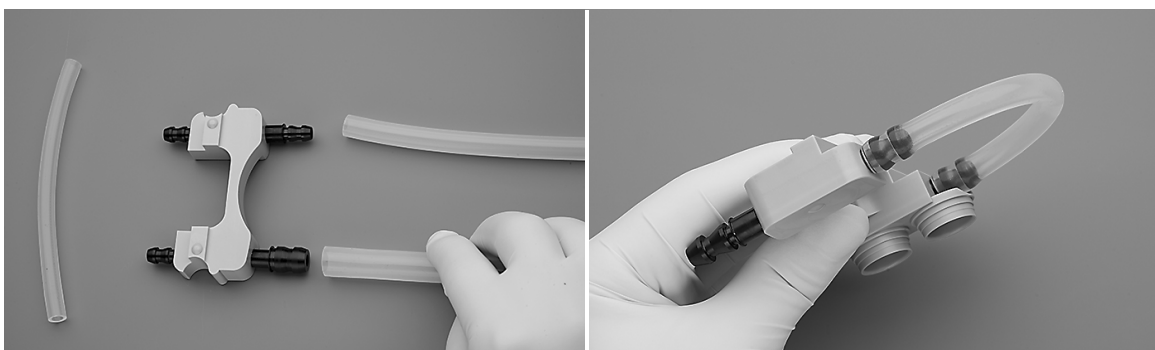
1. Check tubing set for leaks. Do not use leaky tubing sets.
2. Make sure that the tubes of the tubing set are not kinked and are securely fastened.
3. Check that the product is functioning properly and is in good working order.
4. Check labels for readability.

5.4 Assembling tubing sets (UP007 and UP008)

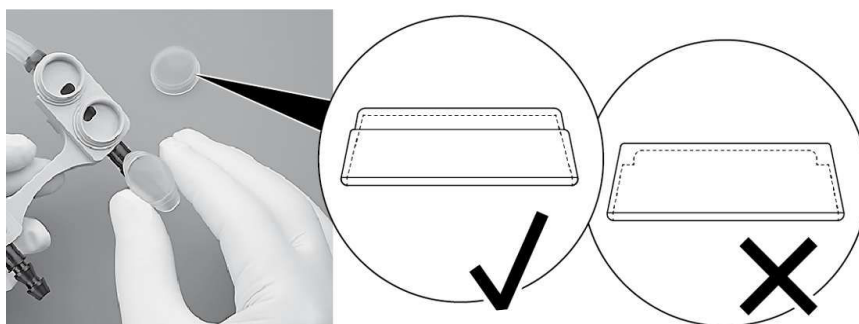
⚠ WARNING

Incorrect tubing sets! Risk of injury!

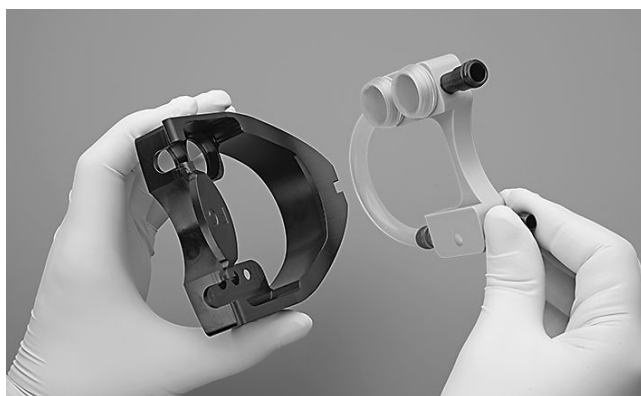
- Use the tubing sets only for the specified application.
1. Attach the pump tube to both top ends of the cassette body. Do not twist the pump tube in the process.



2. Assemble the two pressure membranes. Make sure that the membranes are not upended in the process. The edge of the membrane must be on the outside.



3. Place the cassette body in the inner part.

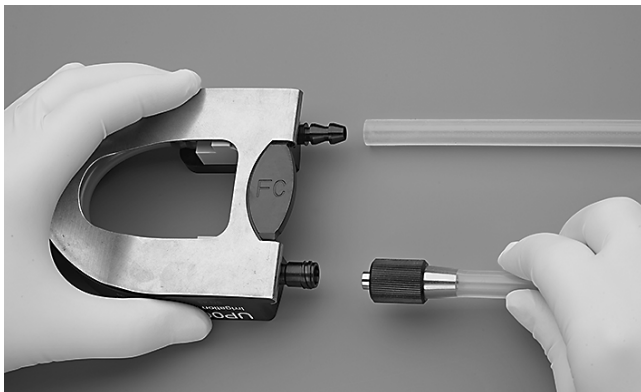


4. Press the metal housing onto the inner part until the clip engages.

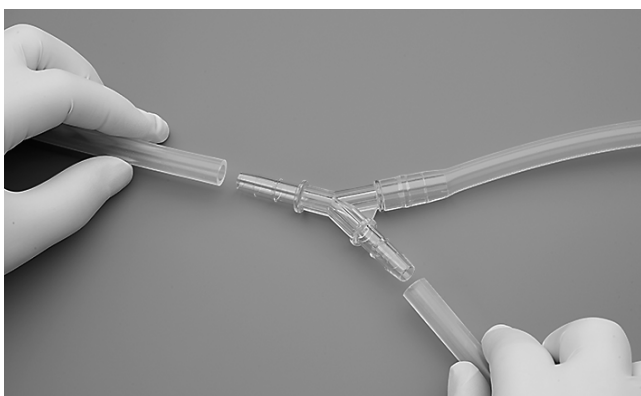


5. Attach the irrigation bottle tube to the connector on the cassette body.

6. Screw the patient tube to the cassette body.



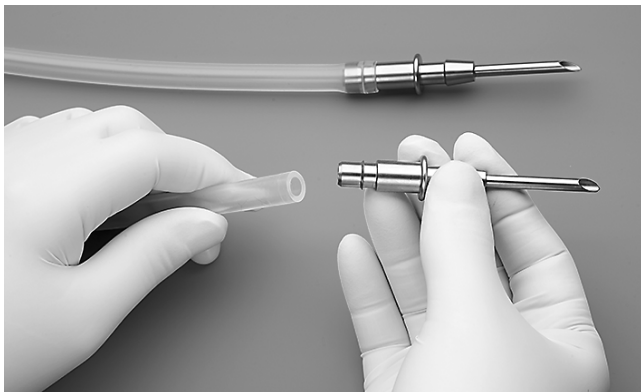
7. Attach the tubes to the T-connectors.



8. Fasten the LUER-Lock connector to the patient tube.



9. Fasten the metal mandrels to the open tube ends.

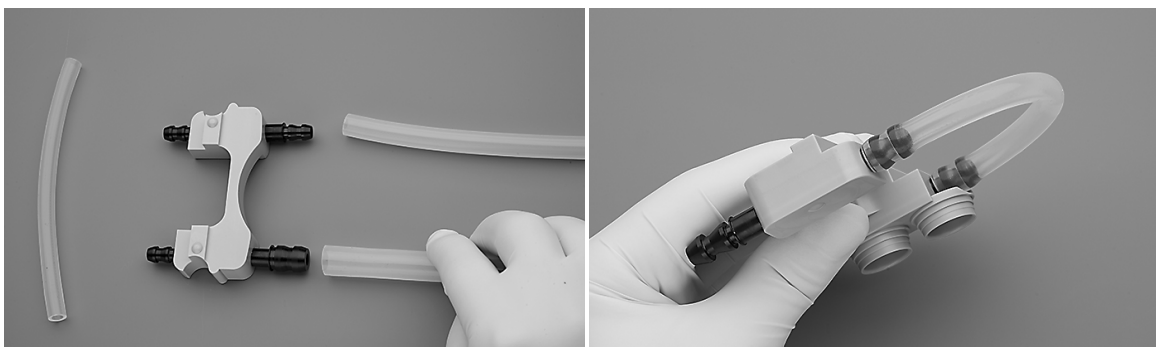


5.5 Assembling the tubing set (UP009)

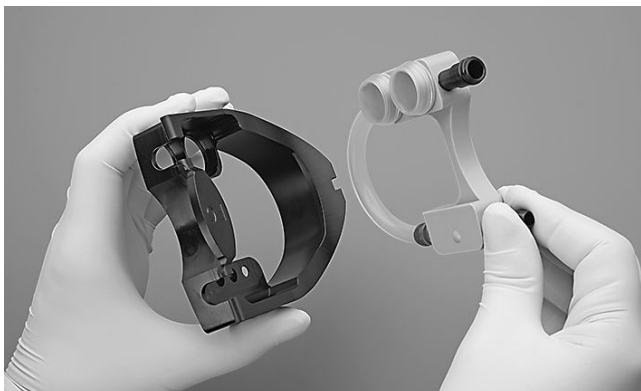
⚠ WARNING

Incorrect tubing sets! Risk of injury!

- ▷ Use the tubing sets only for the specified application.
1. Attach the pump tube to both top ends of the cassette body. Do not twist the pump tube in the process.



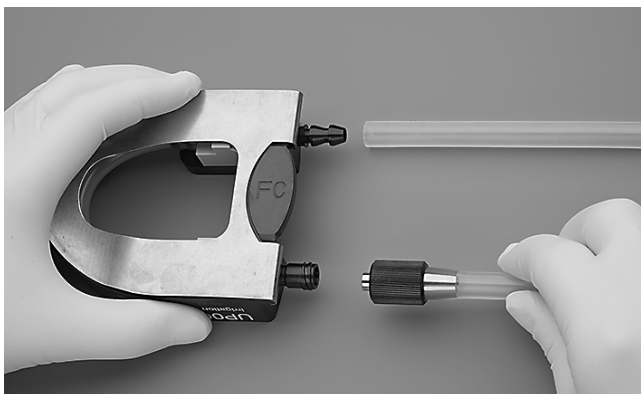
2. Place the cassette body in the inner part.



3. Press the metal housing onto the inner part until the clip engages.



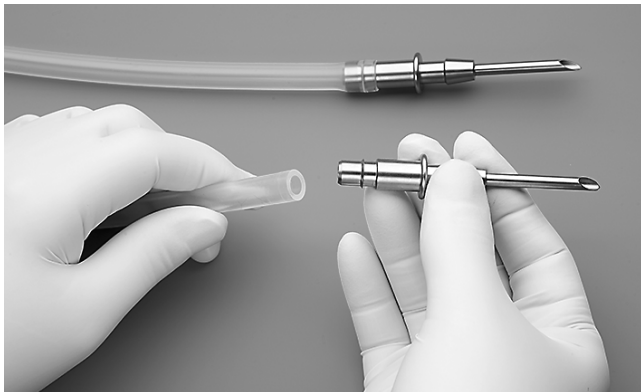
4. Attach the tube for the irrigation bottle to the connection on the cassette body.
5. Screw the patient tube to the cassette body.



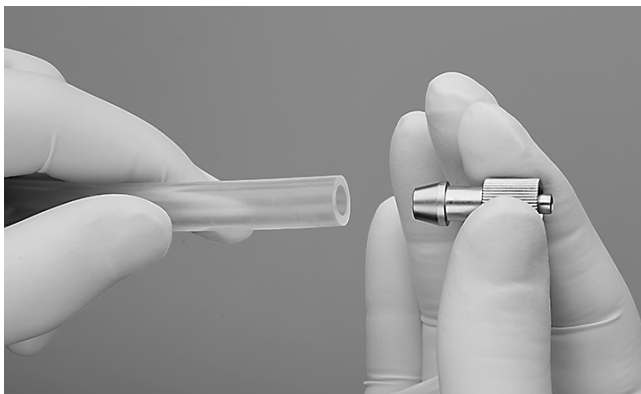
6 Disassembly

6.1 Disassembling tubing sets (UP007 and UP008)

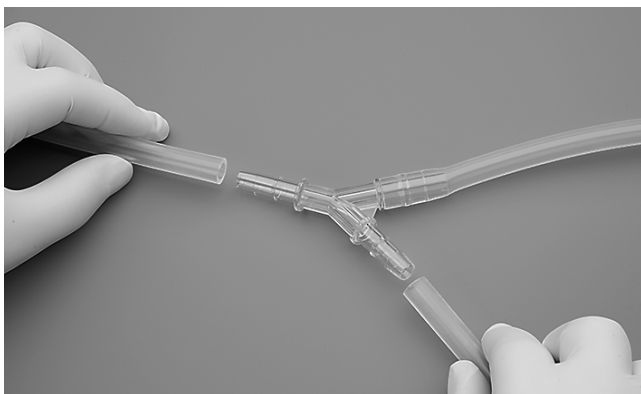
1. Pull the metal mandrels out of the tube ends.



2. Remove the LUER Lock connector.

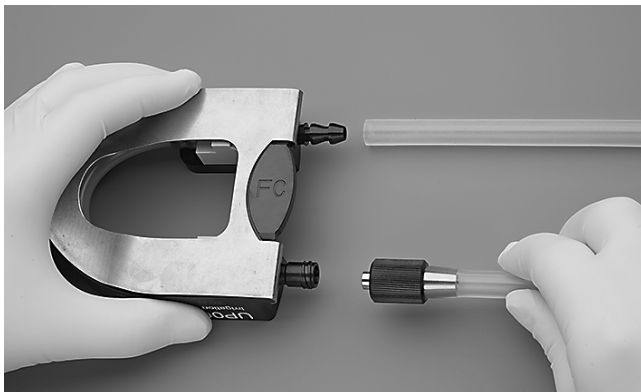


3. Completely remove the tubes from the T-connector.



4. Loosen the patient tube.

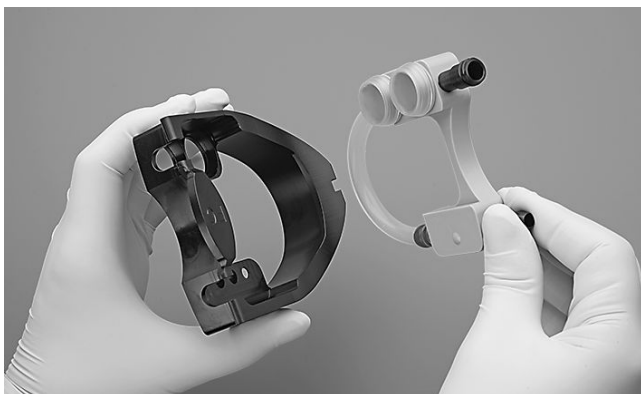
5. Pull off the irrigation bottle tube.



6. Detach the metal housing by pulling gently on the clip.



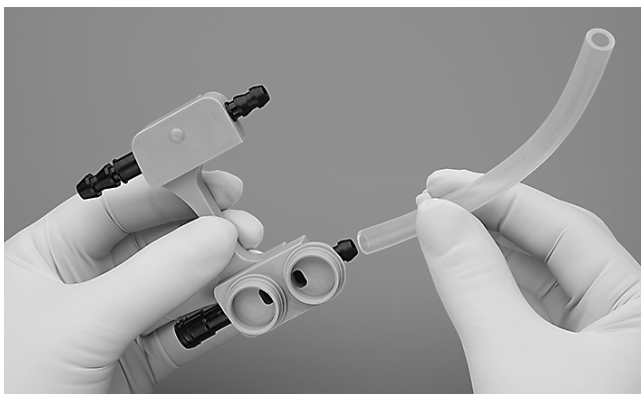
7. Remove the cassette body from the inner part.



8. Remove the pressure membrane.

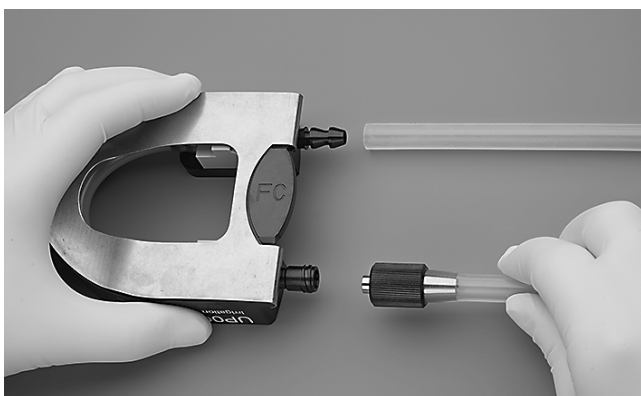


9. Pull the pump tube off both ends.



6.2 Disassembling the tubing set (UP009)

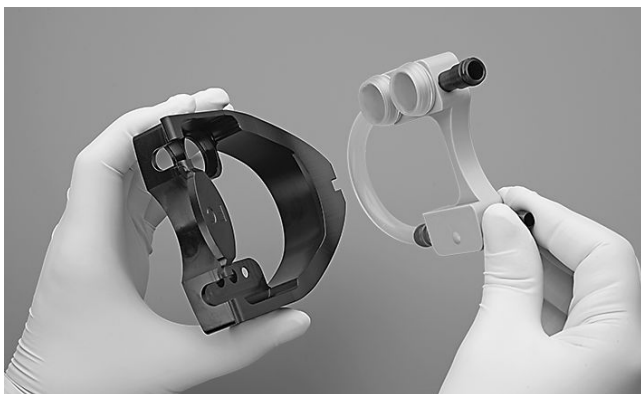
1. Loosen the patient tube.
2. Pull off the tube to the suction container.



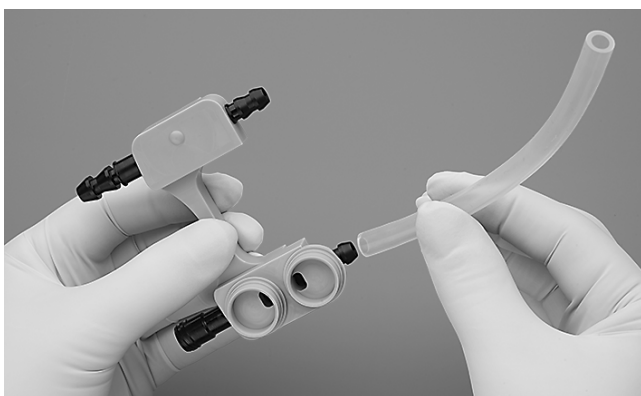
3. Detach the metal housing by pulling gently on the clip.



4. Remove the cassette body from the inner part.



5. Pull the pump tube off both ends.



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 Maintenance

Interval	Activity
after 7 applications	Replace pump tube (UP013) and membranes (UP014)

7.3 Disposing of the product

For disposal, the following measures are necessary:

1. Both damaged products with pointed or sharp edges and pointed or sharp objects must be collected and disposed of in suitable waste containers.
2. Decontaminate the products prior to disposal.
3. Country-specific national laws and regulations must be observed.

8 Accessories and spare parts

8.1 Spare parts

Item	Order no.
Pump Tube	UP013
Membrane	UP014

9 Subsidiaries

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ADS666 • EN • V2.0 • 12-2025 • IFU • CE-MDR



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