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MEDIZINISCHE GERÄTE
APPAREILS MÉDICAUX
MEDICAL DEVICES

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Catheter valves

Instructions for use

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CE **1250**

Table of contents

1 Product information

1.1 Summary information

Max Stäubli AG catheter valves are intended for the sealing of urinary catheters.

- The valve forms a closed system with the indwelling catheter.
- The KV 100 EH and KV 200 EH models can be operated one-handed.
- Catheter valves consist of a polyamide, spring steel and silicone connector.
- The catheter valves are delivered in sterile and individual packaging (process: ethylene oxide (EO)).

The KP 200 coupling piece can be used to connect a urine bag to the catheter valve.

1.2 Product name/article number

Type	**Article No.**	**UDI-DI** (GS1 system)	**Name**	**Variant**
KV 100	300000ST	764016111001P	Catheter valve	with bayonet lock
KV 100 EH	300100ST	764016111002P	Catheter valve	with trigger, for one-handed operation, automatic closure
KV 200 EH	300101ST	764016111003P	Catheter valve	with trigger, for one-handed operation, automatic closure and bayonet lock

1.3 Accessories

Type	**Article No.**	**UDI-DI** (GS1 system)	**Name**
KP 200	300200ST	764016111004P	Coupling piece

1.4 Sets

The following set is available

Type	**Article No.**	**UDI-DI** (GS1 system)	**Name**
KV 200 EHKP	300102ST	764016111006P	KV 200 EH for one-handed operation and with KP200 coupling piece

2 General information

2.1 Information about the instructions for use

These instructions for use describe how to attach, operate and care for the device. The safety and handling instructions provided must be observed for the devices to function reliably.

The instructions for use are part of the device description and must be provided to the medical professionals and the patient. They can be obtained online in several different languages from https://www.maxstaeubli.ch/ at any time.

The graphics and images presented in these instructions may differ slightly from the actual design of the device.

These instructions for use must be read carefully before the device is used.

2.2 Liability and warranty

All information and directions for attaching, wearing and operating the devices are provided in view of our prior experience and findings and to the best of our knowledge.

We reserve the right to make technical changes in the course of developing the devices covered by these instructions for use.

In the event of translation errors, the German-language document is authoritative.

The text and drawings presented do not necessarily match the supplied product exactly. The drawings and graphics are not at 1:1 scale.

The manufacturer accepts no liability of any kind for damages or consequences arising from failure to follow the instructions for use.

2.3 Guarantee

Max Stäubli AG guarantees the buyer a sterile product that has been tested with regard to function and impermeability.

The guarantee is voided in the event of any damage caused by improper handling or wilful damage.

3 Safety

3.1 General information

The information in these instructions for use must be followed in order to ensure the safety and performance of our devices.

3.2 Key to symbols

Important safety and device information in these instructions for use is indicated using symbols. It is imperative to follow the instructions in order to avoid personal injury and material damage.

WARNING!

This symbol denotes risks that can lead to health impairment, injury, permanent bodily harm or death.

Caution!

Indicates the need for the user to examine the instructions for use for important safety information, such as warnings and precautions, that cannot be placed on the medical device itself.

NOTE:

This symbol highlights tips and information for the efficient and smooth operation of the device.

3.2.1 Symbols and labels used on the packaging

“Note the instructions for use”
Indicates the need for the user to consult the instructions for use.

“Manufacturer”
Indicates the manufacturer of the medical device in accordance with EU Directive 93/42/EEC or Regulation (EU) 2017/745.

“Authorised representative in the European Community”
Indicates the authorised representative in the European Community.

“Article number”
Indicates the manufacturer’s order number, allowing the medical device to be identified.

“Unique Device Identifier” (‘UDI’)
means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market

“Website with information for patients”
Points to a website where a patient can obtain additional information about the medical device.
NOTE: It is used to indicate the location where the information for the patient can be found.

“Medical device”
Indicates that the item is a medical device

“Date of manufacture”
Indicates the date on which the medical device was manufactured.

“Use by”
Indicates the date after which the medical device may no longer be used.

“Lot, batch number”
The manufacturer’s batch designation, allowing the production batch or lot to be identified.

“Sterilised with ethylene oxide”
The medical device has been sterilised with ethylene oxide.

“Contains no or is free from natural rubber latex”
Indicates that the medical device is free from natural rubber or dry natural rubber latex as a structural material in the medical device or packaging.

“Do not reuse”
Indicates a medical device that is intended for single use or for use on a single patient during a single treatment.

“Do not resterilise”
Indicates a medical device that must not be resterilised.

“Do not use if packaging is damaged”
Indicates a medical device that should not be used if the packaging has been damaged or opened.

“Store in a dry place”
Indicates a medical device that must be protected from moisture.

“Keep away from sunlight”
Indicates a medical device that requires protection from light sources.

CE 1250

This device fulfils the basic requirements of EC Directive 93/42/EEC.
Notified body: Swiss Association for Quality and Management Systems (SQS).

3.3 Safety instructions

Read the instructions for use in their entirety. Keep them for future reference. If the instructions for use are not observed, injury or damage to the device cannot be ruled out. You can find these instructions for use in several different languages at www.maxstaeubli.ch/downloads/.

The valve should not be used in patients with a tendency to form bladder stones, as there is a risk of the valve becoming blocked and the urine no longer being able to drain through the valve. In the event of a risk, or in the presence, of urinary retention symptoms (absence of or decrease in flow through the open valve), the doctor must be consulted.

DO NOT prepare the catheter valve again:
resterilisation can impair the functioning of the device.

A catheter valve is intended for **single use** on a single patient during a single treatment. It is not reusable.

The valve may only ever be used by one individual person.

Max Stäubli AG defines a “single treatment” as the period during which a urinary catheter (Cystofix or similar) forms a closed system with the valve in/on the patient’s body.

Changing the urinary catheter is defined as another treatment. Removing the catheter valve from the urinary catheter is also considered another treatment and requires the use of a new catheter valve in sterile packaging.

3.4 Responsibility of the user (doctor)

Important:
Patients must be instructed and trained by medical professionals in the handling and use of the catheter valves.

The doctor must

- assess the patient’s specific circumstances
- assess the patient’s ability to operate the catheter valve independently with regard to
  - body size: the patient must be able to see the catheter valve in order to be able to operate the catheter valve correctly.
  - motor, cognitive ability: the patient must be able to operate the catheter valve mechanism (opening and closing) correctly.

3.5 Intended purpose

The catheter valve (CV) is used to seal fitted urinary catheters. It is connected to the catheter tube, allowing patients to empty their bladder (micturition) in a self-sufficient, controlled manner. It is used outside the human body.

A catheter valve is intended for single use on a single patient during a single treatment. It is not reusable.

Max Stäubli AG defines a “single treatment” as the period during which a urinary catheter (Cystofix or similar) forms a closed system with the valve in/on the patient’s body. Changing the urinary catheter is defined as another treatment. Removing the catheter valve from the urinary catheter is also considered another treatment and requires the use of a new catheter valve in sterile packaging.

The duration of use of a catheter depends on a number of factors. The catheter change period must be defined by the attending physician.

Max Stäubli AG recommends a maximum duration of use of three (3) months.

3.5.1 Indications

The indications for a catheter valve are

- There are countless indications that necessitate the use of a urinary catheter. Their common characteristic is that the urine needs to be removed from the bladder directly using an indwelling catheter. A catheter valve is used to control drainage, either by the patient or by a healthcare professional.

KP 200 coupling piece:

- The coupling piece is used for connecting a urine bag. This allows the urine to drain without obstruction and the patient to sleep through the night.

3.5.2 Contraindications

Catheter valves are not suitable for

- patients with ureteral reflux
- people with severe cognitive impairment
- people with severe obesity
- people with motor impairment
- uncontrolled detrusor hyperactivity
- renal insufficiency
- small bladder capacity
- the catheter valve must not be allowed to lie on open wounds
- in cases of tendential or suspected formation of urinary stones (bladder or kidney stones) => risk of blockage (urinary retention symptoms) by a spontaneously released urinary stone
- use for too long a period (see section 3.3) can lead to malfunctions and, as a result, to symptoms of urinary retention.

3.5.3 Target group and intended users

Catheter valves are equally suitable for men and women who have been fitted with a short- or long-term urethral or suprapubic catheter.

The valve is fitted to the patient by a medical professional in a clinical environment after a urinary catheter has been fitted.

The valve is operated (opened, closed) by the patient. This is done in the “normal” environment in which the patient is located or able to stay given the state of the patient’s health.

3.6 Risks that can arise from the device

Various metabolic waste products normally excreted in the urine, such as kidney stones, bladder stones or urate crystals, can lead to malfunctions. The catheter valve must always be replaced when the catheter is changed. If the patient is known to have calculosis, the valve should be checked regularly to ensure that urine can flow through it, or replaced if necessary.

In the event of suspicion/symptoms of urinary retention (absence of or decrease in flow through the open valve), the doctor must be consulted.

If the catheter valve or coupling piece comes into contact with injured skin, this can lead to inflammations.

When the catheter valve is closed under unfavourable conditions, skin can become caught in the valve.

In the event of mechanical damage to the catheter valve or parts of it (e.g. the trigger), there is a risk of injury to the skin.

If the catheter valve is deliberately tampered with, e.g. by removing the trigger, it will no longer be possible to operate it one-handed.

In the event of damage to the catheter valve, consult the doctor and arrange a replacement of the valve.

Lying on the catheter valve for too long can lead to decubitus (bed sores).

4 Structure and function

4.1 General description

Max Stäubli AG catheter valves are made primarily from the three materials polyamide (casing), silicone and spring steel. When these materials are processed and assembled correctly, they produce the exact opening and closing mechanism of the catheter valves.

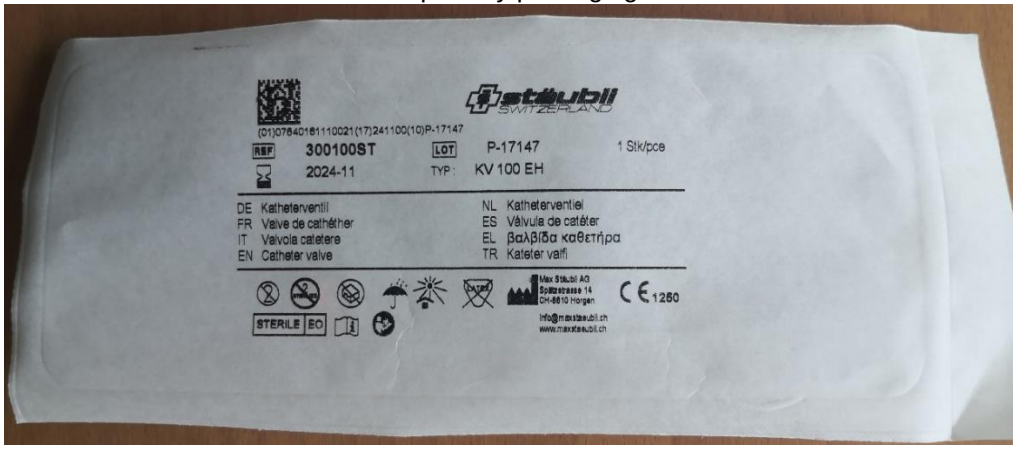
The catheter valves are sterilised using ethylene oxide (EO), thus ensuring asepsis provided that the primary packaging is intact.

4.2 Label

The first label on the secondary packaging is provided for unambiguous identification:

The package insert (quick reference guide) is enclosed with the catheter valve in the secondary packaging:

The catheter valve label can be found on its primary packaging:



4.3 Description

KV 100 (300000ST)

Catheter valve with bayonet lock (for two-handed operation).

Overnight, urine bag connection available with coupling piece.

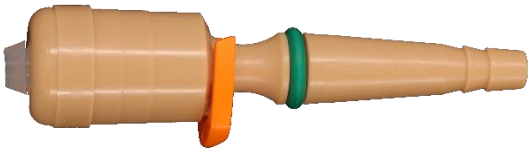
Colour for identification: Green O-ring.

KV 200 EH (300101ST)

Catheter valve with trigger for one-handed operation, automatic closure mechanism and bayonet lock.

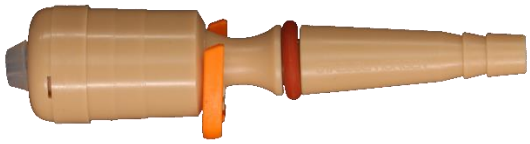
Overnight, urine bag connection available with coupling piece.

Colour for identification: Green O-ring.



KV 100 EH (300100ST)

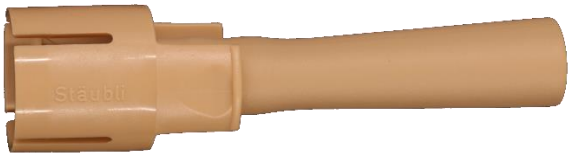
Catheter valve with trigger for one-handed operation and automatic closure mechanism.
Colour for identification: Red O-ring.



4.3.1 Accessories/sets

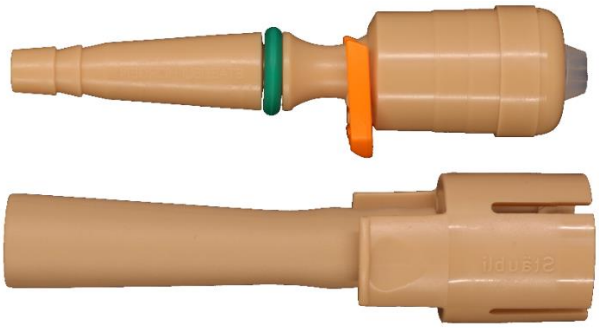
KP 200 (300200ST) Accessory

Coupling piece to connect a bag overnight to KV 100 and KV 200 EH catheter valves.



KV 200 EHKP (300102ST) Set

KV 200 EH catheter valve and KP 200 coupling piece together in sterile packaging.



5 Fitting by a medical professional

5.1 Preparation

Once a urinary catheter has been fitted, the attending medical professional must specify the time at which a catheter valve can be fitted to seal the catheter (prevent continuous flow of urine).

The valve must be fitted by a medical professional, e.g. a doctor.

Take care when handling: do not use contaminated valves (e.g. damaged packaging, opened product that has been dropped and is no longer sterile) => risk of infection.

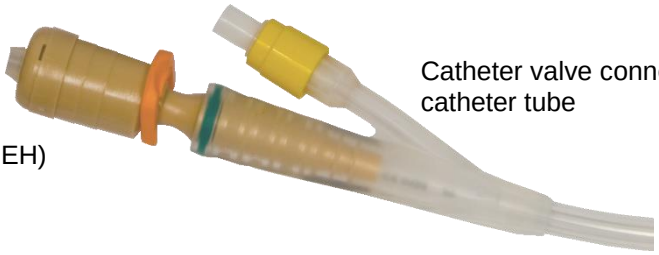
Before removing the catheter valve, check that the primary packaging is intact.

Once the urinary catheter has been successfully fitted and the catheter valve has been connected, the medical professional must check that the system is functioning:
urine drainage and impermeability.

5.2 Fitting the catheter valve

To seal the urinary catheter, insert the conical nipple on the catheter valve into the cone on the catheter tube until the green/red ring is covered.

Catheter valve
(here: KV 200 EH)



Catheter valve connected to catheter tube

Make sure the diameter of the catheter tube fits the valve and forms a seal.
The cone must be dry upon insertion, otherwise the valve will not remain in place.

For instructing the patient, see section 5.5.

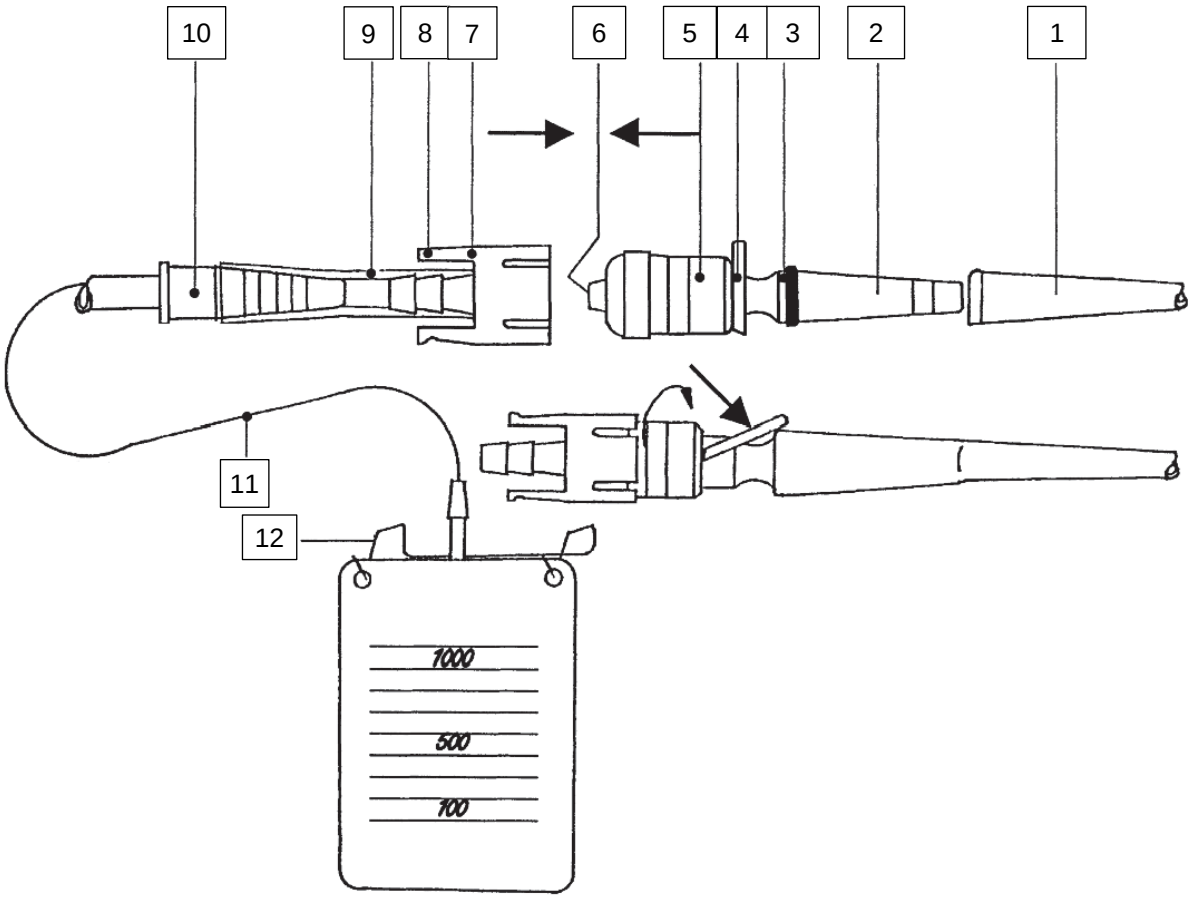
5.3 Removing the catheter valve

When removing the catheter valve from the catheter, it is important to make sure that there is no tension on the catheter tube. When removing the valve, it is extremely important to hold the catheter tube in place to avoid any pain. It is also important to prevent any injury to the patient.

To avoid infection, a closed system must be restored as quickly as possible by fitting a new, sterile valve. Before this is done, the end of the tube must first be cleaned and disinfected as necessary.

5.4 Using the KP 200 coupling piece

5.4.1 Diagram and description



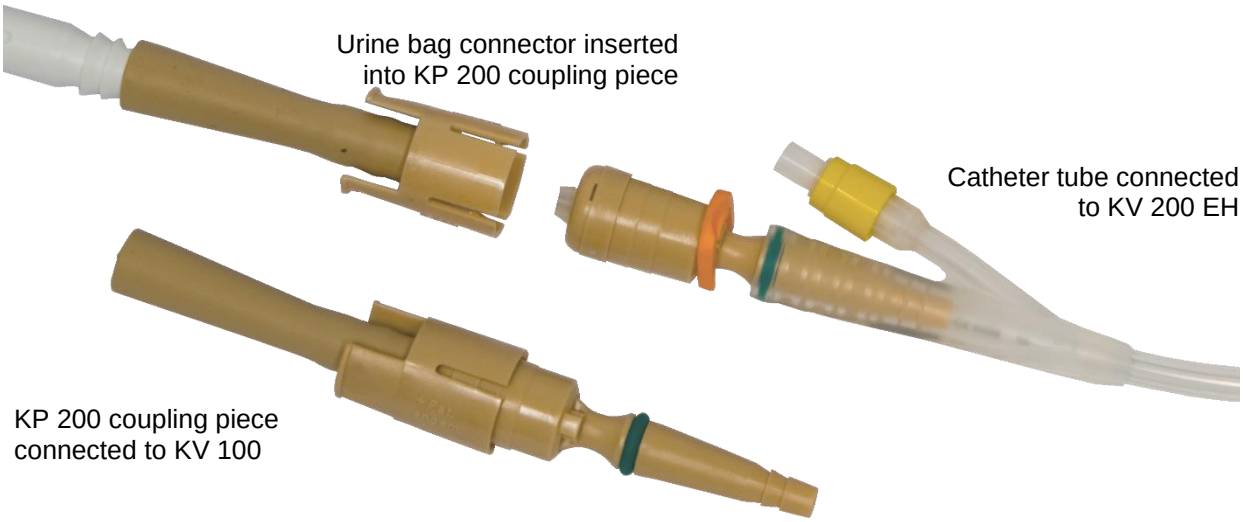
Legend

1	Catheter	7	Coupling piece
2	Nipple	8	Tab
3	O-ring (green)	9	Tube connector
4	Trigger	10	Urine bag connector
5	Sliding sleeve	11	Urine bag tube
6	Outlet	12	Bed attachment

5.4.2 Connecting the coupling piece for the urine bag

All catheter valves with a green O-ring (KV 100, KV 200 EH) can be connected to a urine bag together with the KP 200 coupling piece.

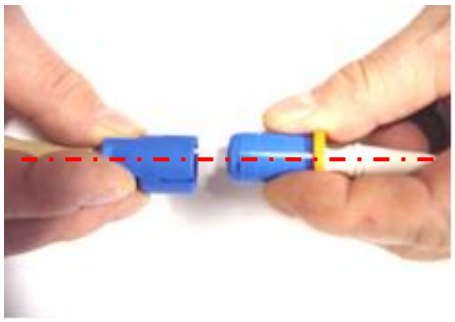
All operations must be carried out with the catheter valve closed.
Make sure the diameter of the urine bag tube fits the coupling and forms a seal.



Connect the KP 200 coupling piece to the end of the urine bag tube.

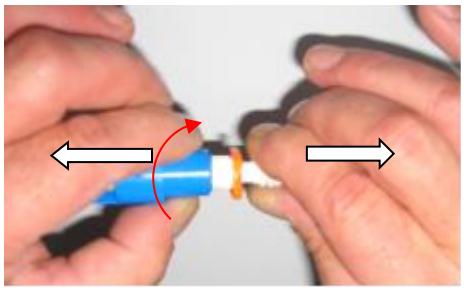
Connecting the coupling piece to the catheter valve:

The KP 200 coupling piece and the catheter valve (KV 100 or KV 200 EH) must be exactly aligned with each other and pushed together until a click is heard.



Opening the catheter valve:

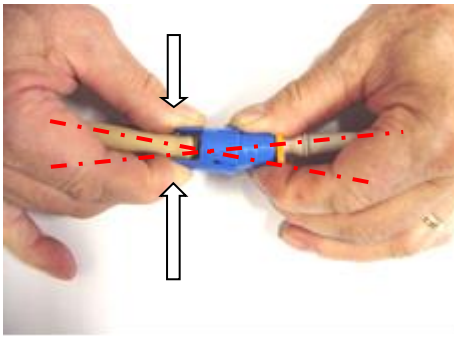
Hold the valve at the tapered end with one hand and pull the sleeve all the way forward with the other hand. Rotate while pulling so that the valve remains open.

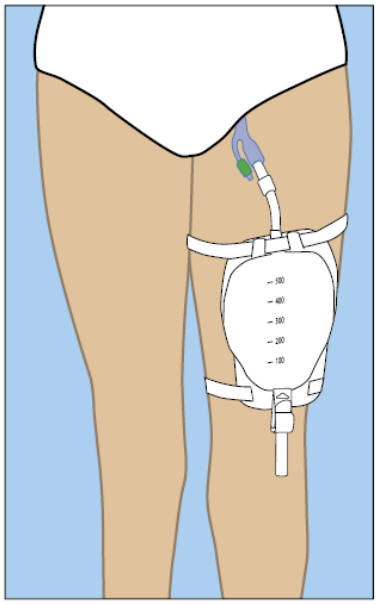


The coupling piece must not be twisted any further after connection.
If this happens, the catheter valve will seal again and the flow of urine will no longer be ensured.
Risk of urine retention symptoms.

Removing the coupling piece:

Press the two tabs together gently, tilt the coupling piece slightly and pull it out.





Example of the use of a urine bag connected to the urinary catheter via a catheter valve.

5.5 Instructing the patient

The medical professional must instruct the wearer on how to care for and operate the catheter valve and the coupling piece if one is present.

The contents of section 6 must be explained to the patient.

The possible risks and their consequences must be highlighted:

- No urine flow when the valve is open:
  - The patient should consult the doctor,
  - Experienced users can remove the catheter valve themselves,
    - removal by the user: this may not solve the problem because the catheter may be blocked

If none of the above measures is effective or helpful, the patient must consult a doctor or the accident and emergency unit.

6 Use

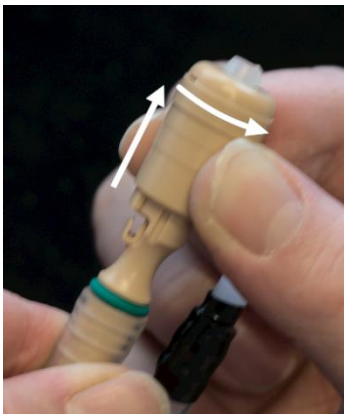
When closing the valve, take care not to trap your finger or skin.

In the event of a risk, or in the presence, of urinary retention symptoms (absence of flow or decreased flow volume through the open valve), a doctor must be consulted.

Always wash your hands with soap before and after handling the catheter, catheter valve and urine bag.

6.1 Operation (opening the valve)

Design with GREEN ring:
(KV 100)

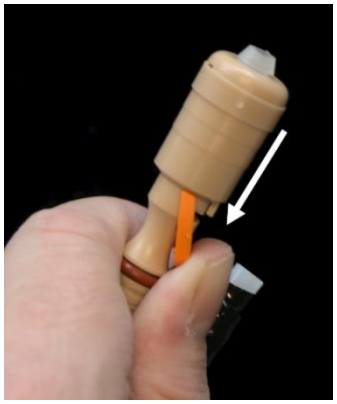


To release urine (opening, two-handed operation):
Hold the catheter valve in place from the conical nipple. Pull the sliding sleeve forwards and gently turn clockwise. The valve will remain open.

To close:
Gently turn the sliding sleeve anticlockwise. The valve will close again.

When closing the valve, take care not to trap your finger/skin.

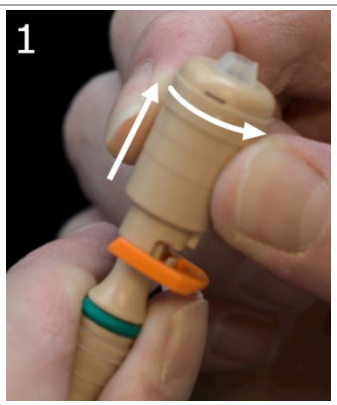
Design with RED ring:
(KV 100 EH)



To release urine (opening, one-handed operation):
Hold the valve as shown in the figure and use your thumb to push the trigger backwards (in the direction of the arrow).

To close:
Once all the urine has drained out, the orange trigger can be released and will close automatically.

Design with GREEN ring:
(KV 200 EH)

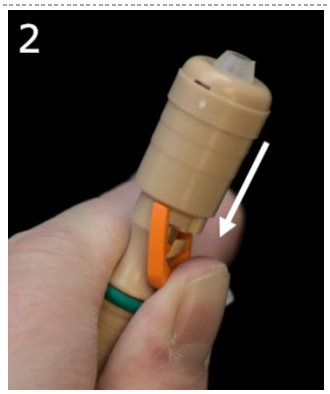


To release urine (opening, two-handed operation):
Hold the catheter valve in place from the conical nipple. Pull the sliding sleeve forwards and gently turn clockwise. The valve will remain open.

To close with both hands:
Gently turn the sleeve anticlockwise. The valve will close again.

OR (one-handed operation):
Hold the valve as shown in figure 2 and use your thumb to push the trigger backwards (in the direction of the arrow).

To close with one hand:
Once all the urine has drained out, the orange trigger can be released and will close automatically.



When closing the valve, take care not to trap your finger/skin.

6.2 Duration of use

The duration of use corresponds to the catheter replacement cycles/intervals (see also sections 3.3 and 3.5).

However, a valve must always be replaced:

- when the catheter is replaced (doctor's visit)
- as soon as the drainage speed decreases (lower flow)
- approximately three months after fitting to the catheter

6.3 Possible faults and troubleshooting

The following faults may occur and are known potential residual risks:

Fault/ malfunction	Effect	Possible cause	Workaround/action
Valve not impermeable	Urine draining uncontrollably	Spring tension has decreased because the valve has been used/worn for too long	Replace the catheter valve.
System not impermeable	Urine draining uncontrollably	The urinary catheter tube does not fit the diameter of the catheter valve: does not form a seal	Consult a doctor to fix the cause of the problem.
No seal between the coupling piece and the valve	Urine draining uncontrollably	The coupling piece has not been correctly fitted to the catheter valve	Check that the coupling piece has clicked correctly into place on the valve as described in section 5.4.2, and if necessary remove the coupling piece and reattach.
System impermeable	Urine cannot drain	Catheter valve does not open	Remove the catheter valve to allow the urine to flow, with assistance from others if necessary. If this is not possible, seek medical treatment immediately. Reseal the catheter with a new valve.
		Possible residue in the system: tube or valve blocked	Remove the catheter valve to allow the urine to flow, with assistance from others if necessary. Then consult a doctor to determine the cause of the blockage and take appropriate action.
		Kinks in the tubes	Straighten the kinks; if this does not help, take action as above.
Catheter valve damaged	Trigger has broken off	Risk of injury, more difficult to handle, one-handed operation no longer possible	Valve can still be opened by pulling (two-handed operation, see section 6.1). The valve must be replaced.
	Trigger is hanging loose	More difficult to handle, one-handed operation no longer possible	

To avoid infection after the catheter valve has been removed, a closed system must/should be restored as quickly as possible by fitting a new, sterile valve. Before this is done, the end of the tube must first be cleaned and disinfected as necessary.

6.4 Product Complaints

Healthcare professionals or users of our catheter valve who have complaints, or who are not satisfied with the quality, identity, durability, reliability, safety, efficacy and/or performance of the product should report this to the responsible dealer or Max Stäubli AG.

If the catheter valve is defective (i.e., does not meet one or more functional specifications or does not work as expected in any other way) or if a defect is suspected, the responsible dealer or Max Stäubli AG must be informed without delay.

Should a malfunction of a catheter valve ever lead to a “serious incident”, which we understand to mean complications that go beyond the potential dangers, risks and warnings described in these instructions, and that this malfunction directly or indirectly led, might have led, or might lead to

- 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 person concerned must inform Max Stäubli AG and the authorities in his or her country without delay.

For every complaint, please indicate the name and article number REF of the component, the lot number LOT, your name and address, and the nature of the complaint.

7 Cleaning the catheter valve, personal hygiene

Max Stäubli AG catheter valves are **single-use products**. They are to be cleaned while connected.

- Clean the catheter valve and genital area at least once a day with water and pH-neutral soap. Replace the washcloth daily or use single-use washcloths.
- Remove incrustations: these can be sources of infection.
- Showering and bathing are permitted. When doing so, clean the catheter valve under running water.
- Remove the **coupling piece** and rinse well with hot water and clean with pH-neutral soap.

8 Lifetime

“Date of manufacture”

This symbol indicates the date (month/year) on which the medical device was manufactured.

“Use by”

This symbol on the packaging indicates for how long the device is usable. After this date, it is no longer possible to ensure that the medical device is sterile.

The device must not be used after this date.

A catheter valve is intended for **single use** on a single patient during a single treatment. It is not intended to be reused.

See also the notes in sections 3.3, 3.5 and 6.2.

9 Accessories and spare parts

Coupling piece KP 200 (article number 300200ST) is available for purchase as an accessory for the catheter valves with green sealing rings. It is used for connecting a urine bag.

There are no spare parts for the catheter valves.

10 Transport, packaging and storage

Because these are sterile medical devices, the storage and transport conditions should be appropriately clean.

“Do not use if packaging is damaged”
Packaging must not be damaged by transport and storage.
Products with damaged or opened packaging can no longer be used.

“Store in a dry place”
Store in a dry place protected from moisture.

“Keep away from sunlight”
Do not store directly under light sources; protect from sunlight.

11 Technical data

Product/component	Active substance
Catheter valve body, coupling piece	POM (Delrin)
Valve	Silicone
Spring	Spring steel

The devices are free from phthalates and substances of animal or human origin.

12 Return and disposal

The devices can be disposed of via the established systems available to users (household waste).