DEMERSAN

DEMERSAN BIOTECHNOLOGY MANUFACTURING. INDUSTRY AND TRADE INC.

HYDROPHILIC URINARY KIT

Address: ERGAZI MAHALLESI GERSAN SANAYI SITESI TAHSIN KAHRAMAN CADDESI. NO:92 ERGAZİ YENIMAHALLE/ANKARA
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USER MANUAL

PLEASE READ THE USER MANUAL BEFORE USING.

STERILE PRODUCT
STERILIZED WITH ETHYLENE OXIDE
SINGLE USE ONLY

PRODUCT IS NOT SUITABLE FOR RE-STERILIZATION.

IDENTIFICATION OF HYDROPHILIC URINARY KIT AND PURPOSE OF USE

The hydrophilic catheters which are produced by DEMERSAN Inc., are manufactured from medical plastic material. Raw material used in the production of hydrophilic urinary catheters is PVC. PVC, which is selected for product production, is suitable for the production of medical products and biocompatibility tests of the products are available.

Hydrophilic urinary catheters are formed by coating the catheter produced from PVC with a hydrophilic solution. There are two cross-side holes. The purpose of this coating solution is to ensure that the product is wetted with water prior to use so that the product can enter the urethra path more easily. Next to the coated catheters, water socket, ring, sheath are placed. Then this product is placed in inner packages including medical paper and film. After being sterilized with ethylene oxide, it is put into 15 outer packages and presented to the market as sterile and disposable.

Water Socket: Water is passed through UV after passing through reverse osmosis and then filled in Aluminium foil packages with a volume of 20-21 cc. It can not be sold alone. It is only contained in the package next to hydrophilic catheters.

Alcohol swap wipes: Wipes in sizes of 17X12 cm, containing 70% ethyl alcohol. Single pack with aluminum foil. It can not be sold alone.

Urine Bag: Made of PVC raw material with a volume of 800 ml.

GMDN Code:36125

Product Code Number: GH50

Inner package includes:

1 hydrophilic catheter

1 water socket

1 alcohol swap wipes

1 urine bag

PRODUCT MEASUREMENTS, DIAMETERS AND COLORS ACCORDING TO INTERNATIONAL CATHETER CODING

	Diameter	Color	REF NO
MALE	CH 06		4006
	CH 08		4008
	CH 10		4010
	CH 12		4012
	CH 14		4014
	CH 16		4016
	CH 18		4018
FEMALE	CH 12		2012
	CH 14		2014
	CH 16		2016
	CH 18		2018
PEDIATRIC 30 CM	CH 06		3006
	CH 08		3008
	CH 10		3010
PEDIATRIC 20 CM	CH 06		2006
	CH 08		2008
	CH 10		2010

The products with reference number 2006-2010 / 3006-3010 are used for children, 2012-2018 are for women and 4006-4018 are for male patients.

PURPOSE OF USE

It is used for bladder evacuation in the postoperative period, during inpatient treatment, in patients with spinal cord paralysis or in case of inability to urinate; reduction of bladder distention related discomfort; sterile urine sample collection, prevention of urine leak during surgical procedures; elimination of postoperative urinary retention; monitoring of hourly urine output; ensuring that the bladder can be washed continuously or intermittently and protection of the region in patients with incontinence. The product is used by a doctor or a nurse who is authorized

in health institutions. In patients with long-term bedridden, in need of care or in patients with spinal cord palsy; the patient's relatives or the patient himself can be used with a few minutes of training given by the nurse. The follow-up of the product use of these patients is made officially by the physician of the patient.

PRODUCT SHOULD NOT BE DEFINITELY USED FOR OTHER PURPOSES.

EFFECT MECHANISM OF PRODUCT

Urinary system; consist of kidneys, ureters, urinary bladder and urethra (urinary canal).

Urine is produced in the kidneys. One ureter (urine tube) comes out of each kidney and ends down in the bladder. Urine that is formed in the kidneys is carried through the ureters to the bladder. Bladder is a hollow and muscular organ located in the lower part of the abdominal cavity. Bladder is also a place of storage of urine in the body. When the urine accumulated in the bladder reaches a certain volume, urine sensation is formed and urine is excreted through the urethra voluntarily. Urinary system is a detailed recycling and waste removal system. The urinary system also plays an important role in the binding of the blood volume in the body.

Diseases and injuries can cause damage to the urinary tract and the storage and discharge function of the bladder can be affected.

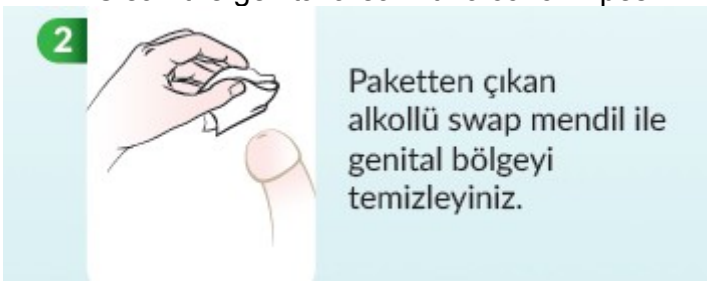
For storage of urine; the bladder muscle should be loose during storage and the sphicter, muscular structure controlling the bladder outlet, should be constricted. During normal voiding, the bladder muscle should be contracted to pump the urine and the sphincter should relax to allow urine to flow. If the bladder muscle is overactive during storage and the sphincter does not contract enough, urine cannot be stored in the bladder and urinary incontinence occurs. If the bladder muscle still does not work well enough during urine storage and the sphincter is over-constricted, the urine cannot be pumped out and the bladder does not drain completely. In cases where spontaneous urine cannot be excreted, the patient's urine should be evacuated by external intervention.

After giving supine position in men and dorsal rectum position in women; catheter is pushed slowly through the urethra until the flow of urine and the bladder is completely emptied. When the urine is finished, the catheter is removed. Here, the catheter loosens the sphincter, which is excessively constricted, it allows the bladder muscle to contract, the bladder outlet is opened and the urine is discharged from the catheter.

HYDROPHILIC URINARY KIT USAGE

Wash your hands

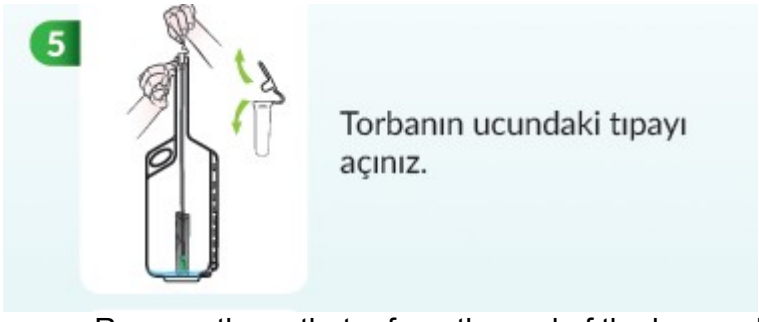
- Clean the genital area with alcohol wipes.



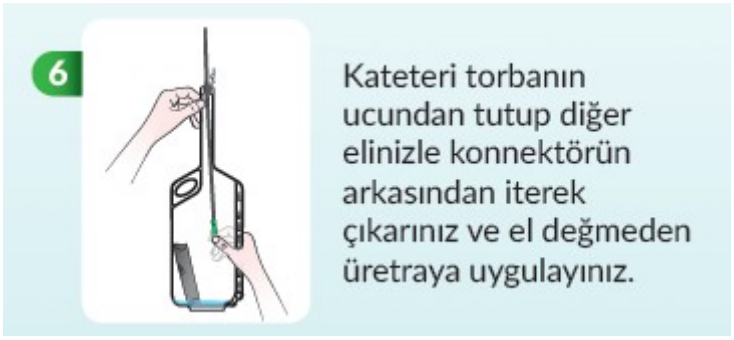
- Blow the water socket with two hands without twisting as shown in the picture.

- After exploding the water socket, shake the water for 45 seconds in the package to ensure that the probe is slippery.

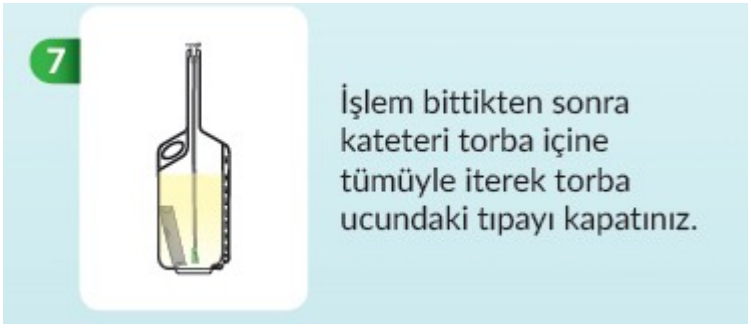
- Open the plug at the end of the bag.



- Remove the catheter from the end of the bag and push it from the back of the connector with the other hand and apply it to the urethra.



- Close the plug at the end of the bag by pushing the catheter completely into the bag after the end of the procedure.



- In order to empty the bag; open the plug at the bottom end and empty. Throw the bag into the trash.

INDICATIONS

This can be used in cases where neurogenic bladder occurs such as Spina bifida, multiple sclerosis, spinal cord injuries, spinal tumors, intervertebral disc herniations, diabetic neuropathy; after urinary diversions; in cases with obstructive uropathy, hypotonic bladder, detrusor-sphincter discoordination. Purpose of use in these diseases is to provide adequate drainage, reduce intravesical pressure, prevent incontinence, prevent urinary system infections and protect the kidneys, evacuate bladder in the postoperative period, during inpatient treatment, in patients with spinal cord paralysis or in case of inability to urinate; reduce bladder distention related discomfort; collect sterile urine sample, prevent urine leakage during

surgical procedures; eliminate postoperative urinary retention; monitor hourly urine output; ensure that the bladder can be washed continuously or intermittently and protect the region in patients with incontinence.

THE BENEFITS OF USE OF HYDROPHILIC KIT URINARY CATHETER FOR PATIENTS

- Product is sterile, disposable
- No additional water is needed
- Available in 45 seconds
- Provides unlimited comfort throughout the day
- Protects glide during catheterization
- Prevents trauma due to rounded tip

CONTRAINDICATIONS

The use of catheters is generally not appropriate for the following patient groups;

- Patients without hand skills due to the severity of neurological pathology,
- patients with urethral stricture
- Patients with false passages
- patients with autonomic dysreflexia

WARNINGS / PRECAUTIONS

The principles to be considered when installing a catheter;

- Long-term paralyzed patients can use this device after training by a doctor or nurse
- The device can be applied by specialist doctors and nurses.

- The device is not intended for treatment. It is a temporary use period invasive device used to evacuate the bladder only.

- Only specialist doctors and nurses use in infants and children.

- It is not inconvenient for pregnant and nursing mothers.
- **Periodic use should not exceed 30 days in patients who do not have a feeling of urine**.

Long-term users are kindly requested to inform us about the problems encountered in product performance during use by sending mail to demersan@demersan.com.tr and calling us from +90 312 255 08 86.

Do not use products in damaged packages.

It is for single use only. Do not use the device more than 1 time. Dispose of the product as medical waste. Sterilized by ethylene oxide. Do not re-sterilize. If the package has been opened and damaged; do not use. Not available after the expiration date on the package.
Store at 16-30 ° C

Store in a dry place

Do not expose to the sun.

Take care not to use after excessive urine accumulation.

Please visit www.demersan.com.tr for up-to-date information.

SIDE EFFECTS / ADVERSE EFFECTS

- Itching
- bleeding, hematoma
- Urinary tract infections
- False passage
- Blader perforation

APPLY YOUR DOCTOR WHEN AN UNEXPECTED EFFECT IS SEEN

ADVERSE EVENT NOTIFICATION FOR THE DEVICE

Any adverse events related to these urinary catheter products with hydrophilic rings must be notified to DEMERSAN BIOTECHNOLOGY MANUFACTURING. INDUSTRY AND TRADE INC. Please call 0312 255 08 86.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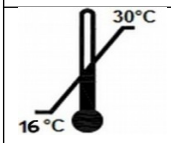
For the safe use of the devices in accordance with Regulation 93/42 of the Medical Devices Directive, the information on the label supplied with the device or on the instructions for use must be explanatory. According to Annex II 13.3 of the Medical Devices Directive; the descriptions of the signs on the product labels are shown as follows according to TS EN ISO EN 15223-1 and TS EN 1041 standards.

	DO NOT USE AGAIN
	DEMERSAN BIOTECHNOLOGY MANUFACTURING. INDUSTRY AND TRADE INC. Products Production date (day / month / year)
	DEMERSAN BIOTECHNOLOGY MANUFACTURING. INDUSTRY AND TRADE INC. Products Expiration date (day / month / year)
	PRODUCT CATALOG CODE
	STERILIZED WITH ETHYLENE OXIDE.
	TEMPERATURE LIMITS (LOW AND HIGH TEMPERATURE LIMITS 16-30° C)
	DO NOT EXPOSE TO THE SUN
	KEEP DRY
	DO NOT STERILIZE TWO TIMES
	DO NOT USE DAMAGED PACKS
	LOT NO
	MANUFACTURER COMPANY INFORMATION

	USER GUIDE
EC REP	**European Authorised Representative:** EC REP WELLKANG LTD., 16 CASTLE ST., DO VER , CT 16 1PW, UK; Phone:+44(20)32876300 (ext:1), www.ce-marking.eu; aufhrep@ce-marking.eu
	Approved Company (Competent Authority) Identification Number, Name and Address: 2292, UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi ve Ticaret Limited Sirketi, Mutlukent Mah. 2073 Sk. No:10 Umitkoy - Cankaya - ANKARA