INSTRUCTIONS FOR USE

T-Control® CE 0123

Rethink Medical SL.
Calle Practicante Ignacio Rodríguez S/N
Las Palmas de Gran Canaria, Las Palmas,
CP 35017, Spain.

rethink medical

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INSERTION

Please read the following instructions before using T-Control®:

Step 1

Before catheter insertion, the patient's urethral meatus or vulva should be cleaned and disinfected according to your unit's current protocol **(Fig.1)**.

Step 2

Wearing sterile gloves and always following the appropiate aseptic technique, open the sterile catheter package **(Fig.2)**, take the catheter and use a needle-free syringe to check if the balloon can be filled and emptied **(Fig.3)** with the volume of sterile water, indicated on the catheter and the label of the bag.

Warning: Do not change the position of the catheter valve yet, because it is in the correct position for the **INSERTION** process.

Step 3

Lubricate the catheter according to current health protocol. Among the options, we highlight the lubrication of 3-4 cm from the catheter tip **(Fig.4)** or the lubrication through the patient's urethral meatus **(Fig.5)**.

Step 4

Insert the catheter into the bladder approximately 3-4 cm to place the balloon completely in the bladder **(Fig.6)**. Generally, resistance will be detected when reaching the bladder and once the catheter is inserted inside, the urine will begin to flow through the tube of the catheter unless the bladder is empty **(Fig.7)**.
Urine will flow into the valve within 5 to 20 seconds, depending on the amount of urine accumulated in the bladder. If it takes longer than 20 seconds for the urine to flow, turn the valve to the OPEN position.

Step 5

Once the urine is visually observed to be falling, the balloon can be filled with 10cc of sterile water using a needle-free syringe **(Fig.8)**.

Step 6

Gently pull on the catheter to check that the balloon is attached to the bladder **(Fig.9)**.

Step 7

Once the balloon is filled, operate the valve preferably with three fingers (as indicated in the image) until it passes from the **INSERTION** to the CLOSED position, the red colour remaining visible and the white safety cap at the other end of the green part falling off of the valve **(Fig.10)**.

Warning: This cap has no use once the valve has been activated for the first time, so it has to be discarded.

URINE SAMPLING

To collect the sample, place a sterile urine collection container on a flat surface without inserting the catheter cone inside the container or letting it touch its wall **(Fig.11)**, turn the valve to the OPEN position, leaving the green colour visible **(Fig.12)**.
After taking the sample, move the valve back to the CLOSED positon **(Fig.13)**.

EMPTY THE BLADDER WITH T-CONTROL®

Hand washing with soap before handling the catheter is recommended.

Step 1

To empty the bladder, if necessary, while facing the urinal or sitting down, move T-Control® to the OPEN position **(Fig.26)** and **(Fig.27)**.

Step 2

When the urine stops flowing, move T-Control® to the CLOSED position **(Fig.28** and **Fig.29)**.
Dry the catheter cone to prevent urine stains on clothing.

USE OF COLLECTION BAG

Step 1

Before placing the urine collection bag, check that the valve is in the CLOSED position to prevent urine leakage **(Fig.14)**.

Step 2

Connect the collection bag **(Fig.14)** and turn the valve to the OPEN position **(Fig.15)**. The urine will begin to fill the collection bag **(Fig.16)**.

Step 3

If you want to interrupt the continuous drainage to the collection bag to allow the bladder to fill or to prevent possible accidental leaks during patient transfer, mobilisation or any other activities, you can activate the CLOSED position again **(Fig.17)**. Urine will stop flowing into the collection bag **(Fig.18)**.

T-CONTROL® FIXATION

To fix the T-Control® catheter, you have two options:

T-Control® is directly connected to the bag previously attached to the leg. With T-Control® in the CLOSED position **(Fig.19)** the flow of urine to the bag is blocked. When T-Control® goes to the OPEN position **(Fig.20)** the urine begins to fill the bag.

With T-Control® in the CLOSED position, the Holder can be fixed at the end of the catheter **(Fig.21)**, and then you can choose to use a thigh strap as shown in figures **(Fig.22)** and **(Fig.23)** or by directly attaching the Holder to underwear, as shown in figures **(Fig.24)** and **(Fig.25)**.

CATHETER REMOVAL

Before removing the catheter, empty the bladder, make sure the valve is in OPEN position and deflate the balloon by aspirating the water from it with a needle-free syringe. Then, gently remove the catheter. Optionally, in case of observing any deflation error or in case of needing rapid deflation of the balloon, you can cut the catheter shaft below the inflation valve to then remove the catheter.

INSERTION AND URINE SAMPLING

*AFTER INSERTION, PROVIDE THE INSTRUCTIONS OF USE TO THE PATIENT

Fig.1

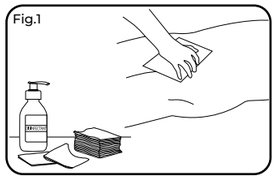


Fig.2

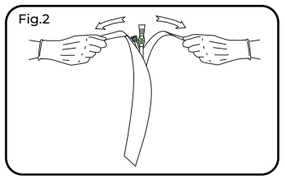


Fig.3

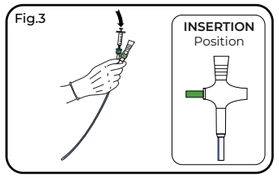


Fig.4

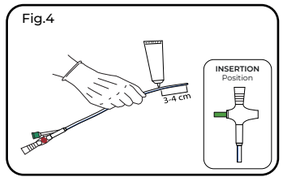


Fig.5

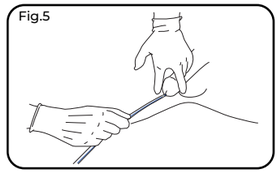


Fig.6

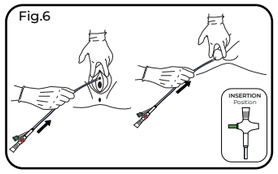


Fig.7

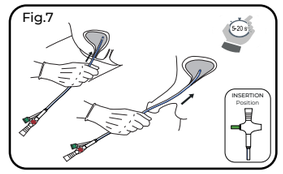


Fig.8

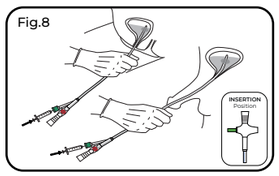


Fig.9

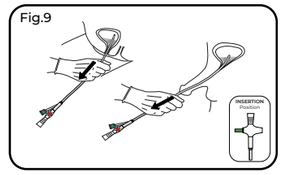


Fig.10

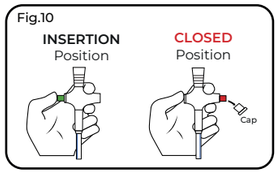
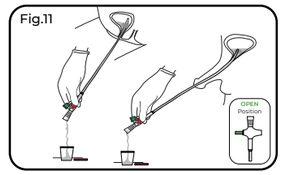


Fig.11



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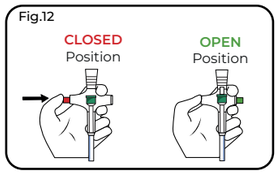


Fig.13

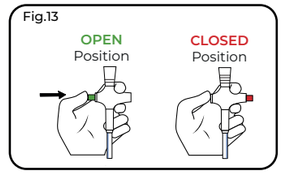


Fig.14

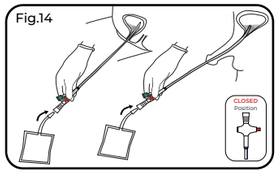


Fig.15

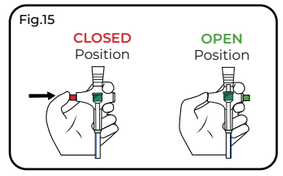


Fig.16

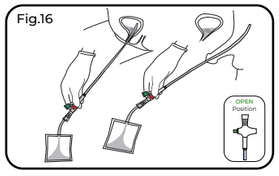


Fig.17

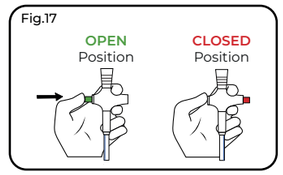
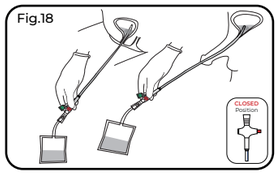


Fig.18



DAILY USE

Fig.19

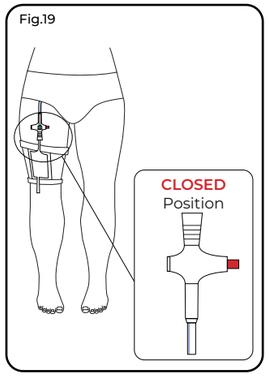


Fig.20

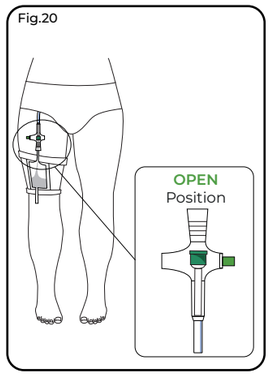
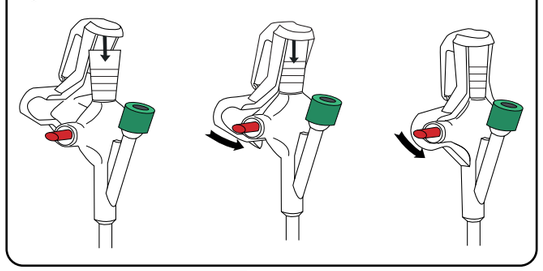


Fig.21



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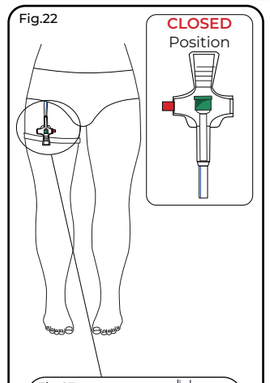


Fig.24

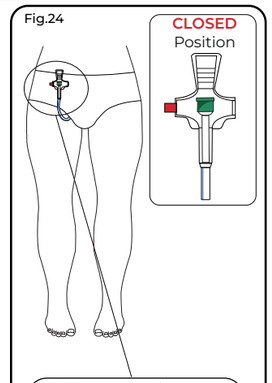


Fig.23

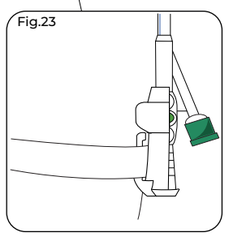


Fig.25

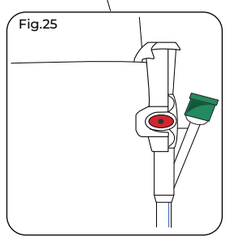


Fig.26

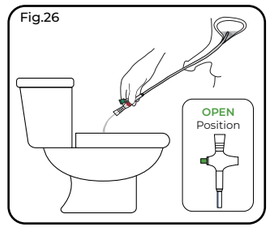


Fig.27

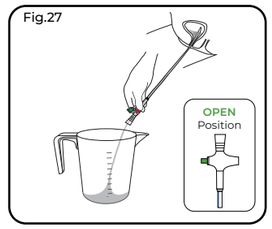


Fig.28

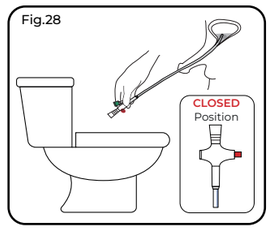
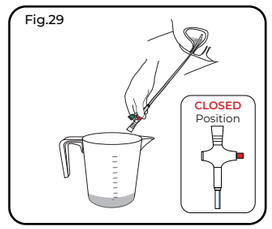


Fig.29



DATA SHEET

Product data
Product or trade name: T-Control® and component Holder
Manufacturer: Rethink Medical S.L.
Model and type: Two-way urethral silicone catheter of 12FR, 14FR, 16FR, 18FR sizes.
Description
T-Control® is a Foley type 2-way silicone urethral catheter with an integrated fluid control valve for indwelling drainage, made of silicone, latex-free, sterile and single-use.
Class IIb product. Sterile by Ethylene Oxide (EO). The sterility of the product is only ensured as long as the package is not opened or damaged and not beyond the expiration date.
The continuous use of a single device of T-Control® cannot exceed 30 days.
The acumulative use for each type of T-Control® device can exceed 30 days.
The Holder is a component for T-Control® that is placed at the external end of the catheter body wrapping the valve on one side.
Presentation
Unit of use: Peelable sealed packaging.
Intended user
Health professionals.
Intended patient population: Adult men and women.
Intended purpose/Indications
T-Control® is a tubular device intended for being introduced into the bladder cavity through the urethra of the patient. It is fixed in the bladder by filling the anchoring balloon to drain urine by intravesical pressure. The clinical benefit of T-Control® is to provide drainage and/or flushing of the bladder.
The use of T-Control® is indicated for different dysfunctions such as urinary retention, incontinence with wounds in the sacrum or in areas that may be in contact with urine and make it difficult to heal, control of urine production, palliative care, surgery and for other functions such as residual volume measurement or obtaining a urine sample. The Holder is a component for T-Control® that facilitates the fixation of the device and prevents residual leakage through the urine outlet port or the entry of liquid or any type of particle into it and also avoids accidental valve opening.

CONTRAINDICATIONS

1) Urinary tract infection (cystitis/urethritis).
2) Injury to the urethra.
3) Urethral stricture.
4) Injury to the penis.
5) Insufficient mental and/or physical capacities to handle the device.
6) Ureteral reflux.
7) Overactive bladder.

SIDE-EFFECTS

Side effects associated with T-Control® are the same as those associated with Foley-type catheters: septicaemia, catheter-associated urinary tract infections (CAUTI) and biofilm proliferation, urethral damage, injury to the bladder, meatus or urethral erosion, narrowing of the urethra, bladder spasms, etc.
If any discomfort or indication of trauma or infection occurs, consult your doctor. Any serious incident that occurs while using the T-Control® catheter should be reported to the manufacturer and local health authorities.

PRECAUTIONS

1) The absence of leaks and the correct filling of the balloon must be checked before use.
2) Make sure the needle-free syringe is properly inserted into the fill valve hole.
3) Check the capacity of the balloon on the individual outer packaging.
4) Do not overfill or underfill the balloon or the catheter could fall off.
5) The balloon can break if it is filled beyond its capacity, impacted by sharp objects or by crystals (such as those produced by physiological serum). Periodically check if the balloon is well anchored, and follow the recommendations of the current health protocol.
6) Make sure that the white safety cap, located next to the green part of the button, is in place before using the catheter and that it falls off when the valve is activated. Be careful when activating the valve for the first time since the cap can be projected in the direction in which it is pointed.
7) Change the catheter in case the valve is blocked.
8) Avoid storing of the product together with chemicals.

WARNINGS

1) For single patient use only.
2) Do not use if package has been opened or damaged.
3) Please use the product immediately after opening the package.
4) The product is intended to be inserted by competent healthcare professionals and aseptic technique should be used.
5) Do not remove the catheter by yourself. This must be removed by a competent professional.
6) Do not use petroleum-based ointments or lubricants, it may damage the catheter.
7) Do not use the product if the balloon is broken.
8) Fill the catheter balloon with sterile water. Do not use needles to fill the balloon.
9) Do not clamp the catheter body, as this may damage the catheter and prevent balloon emptying.
10) Do not use after expiration date.
11) This is a single-use disposable product, any re-sterilization or reuse of the product may pose a danger to the patient.
12) Do not use the catheter without restraint during moderate or intense activity.
13) Keep out of reach of pets.
14) Dispose of the catheter and its packaging in accordance with the national regulations in force.
15) The proper functioning of the device is not guaranteed if it is not used according to Fig. 10, 12, 13, 15 and 17.

HOLDER WARNINGS

1) Can be used multiple times by the same patient.
2) Daily washing with soap and water is recommended.

CONDITIONS OF CONSERVATION

1) Store in its container in a cool, dry place, protecting the product from humidity and excessive heat.
2) Avoid prolonged exposure to light.
3) Store the product in a manner that prevents it from being crushed.
4) If visible sediment is observed in the system, follow the recommendations of the health care professional.

In case of doubt or serious incident please contact: info@rethinkmedical.es

GLOSSARY OF SYMBOLS