Tierrett Foley Catheter

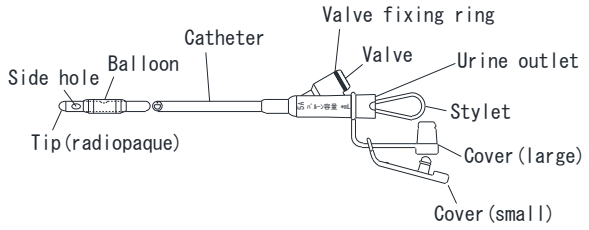
Instructions for use

Contraindicated to re-use

[CONTRAINDICATIONS・PROHIBITION]
Do not reuse the product (single use only).

[Shape, structure, principle]
This product is sterilized with ethylene oxide gas.

<Shape>



・Transparent type

Size	O.D.	Total length	Recommended balloon capacity
6Fr	2.0mm	340mm	1mL
8Fr	2.7mm	340mm	3mL

<Raw Materials>
・Catheter: Silicone rubber
・Stylet: Polyamide

<Principles>
By injecting sterile distilled water from the valve with a syringe, the balloon inflates and can be placed. By sucking the injected sterile distilled water, the balloon shrinks and can be removed. Urine is discharged from the side hole through the lumen to the urine outlet.

[Intended purpose, efficacy or effect]
A flexible tube that is placed in the bladder for short-term use. This product has an inflatable balloon at the distal end. Used for urinary catheterization.

[Operating or using method]
The below is a general procedure.
[1] Disinfect (clean, wipe) the external urethral meatus and vulva.
[2] Remove the product from the packaging material hygienically and apply a lubricant to the catheter as required.
[3] Insert into the urethra and bladder using a stylet.
[4] Confirm that the tip of the catheter reaches the inside of the bladder (passes through the external urethral sphincter muscle) and urine begins to flow out from the urine outlet.
[5] Advance the catheter about 3 cm.
[6] Slowly inject a specified volume of sterile distilled water into the balloon to expand.
[7] Gently pull the catheter so that the balloon hits the bladder neck. If it is doubt that the catheter is inserted correctly, inject 10 to 20 mL of saline solution through the urine outlet and confirm that the saline is discharged immediately after opening the urine outlet.
[8] Remove the stylet slowly. If the urine is left without confirmation of outflow, inject sterile distilled water into the catheter and carefully remove because the inside of the catheter is dry and the stylet is difficult to remove.
[9] Fix the catheter to the skin with a bandage etc.
[10] If necessary, put the catheter urine outlet with the cover (small) on the cover (large), check that make sure to attach by gently pulling the cover (large). When opening the cover (small), make sure to hold the cover (large) and slowly lift the cover (small) knob.
[11] When removing the catheter, suck the sterile distilled water of the balloon with a syringe to shrink the balloon and slowly pull out the catheter.

<Precautions for the using method>
[1] Do not to touch the valve fixing ring.
[The fixing ring may come off and the valve may fall off.]
[2] Please note the following when inflating and deflating the balloon.
1) Use only sterile distilled water to inflate the balloon.
[When saline, contrast medium, etc. are used, the components may coagulate and water may not be removed.]
2) Use a general slip-type disposable syringe to inflate or deflate the balloon.
[With a lock type syringe, it is impossible to insert very inside of the valve. If the taper does not match, the valve will be damaged.]
3) When inflating and deflating the balloon, make sure to insert very inside of the valve and perform the operation.
[If the tip of the syringe is not inserted very inside of the valve, the inside valve may not operate and the balloon may not be perform the operation.]
4) Inflate the balloon slowly and carefully.
[Due to the pressure when injected suddenly, the valve may off and sometimes come off.]
5) Do not inject more than the specified volume of sterile distilled water into the balloon.
[Excessive injection will overload the balloon and cause a burst.]
6) When removing the syringe, make sure to press the valve and rotate the syringe to remove.
[The valve may off and sometimes come off.]
[3] When placing a catheter, after confirming the outflow of urine, insert a sufficient length, then inflate the balloon with a specified volume of sterile distilled water and pull lightly. If it cannot confirm the outflow of urine, inject 10 to 20 mL of saline solution through the urine outlet and confirm that the saline is discharged immediately after opening the urine outlet. Or after checking the outflow of urine after a while, inflating the balloon.
[4] When connecting a tube, etc. to the catheter urine outlet, make sure to select the one fits. During use, make sure no leaks or looseness in the connection part, and use in a securely connected state.
[5] When connecting a bamboo shoot connector, etc. to the catheter urine outlet, insert a bamboo shoot connector, etc. straight along the urine outlet lumen. Do not apply a load such as bending, twisting, or pinching the urine outlet in this state.
[The tip of a bamboo shoot connector, etc. may damage the cavity of the urine outlet, leading to a crack or rupture of the urine outlet.]
[6] When fixing the catheter to the skin, use a bandage etc. and do not fix the catheter directly with a thread.
[There is a risk of blockage or rupture.]
[7] Change the fixation position of the catheter as appropriate.
[8] If the catheter is fixed with a bandage, etc., peel off slowly and carefully when removing the fixation.
[If using a bandage with strong adhesiveness for a small-diameter catheter when peeling off, the catheter may be overloaded and cut.]

[Precautions]

Carefully apply to the following patients;

[1] Confirm in advance if it is applicable to cases with urethral stenosis.
[There is a risk of damage to tissues and urethral mucosa.]

<Important basic caution>

[1] Make sure the stylet is located closer to the tip of the catheter than the side hole before use.
[The stylet may protrude from the side hole and damage the urethral mucosa.]

[2] Manage appropriately the catheter state during placement. If necessary, check the placement state of the catheter by fluoroscopy.
[The catheter lumen may be occluded due to breakage, bending, twisting, urine components, stones, etc.]
[Stones may cause the balloon to burst or natural leaks may cause the balloon to shrink.]
[There is a risk of ulceration, perforation, etc. when the tip of the catheter comes into contact with the bladder wall.]

[3] Remove all the sterile distilled water in the balloon once a week as a guide, inject the specified volume of sterile distilled water again.

[4] When replacing the sterilized distilled water in the balloon, remove all the sterilized distilled water without additional injection, then inject the sterilized distilled water of the balloon capacity again.

[5] Do not pinch the device with forceps too strongly.
[May cause catheter breakage, lumen blockage, and balloon breakage.]

[6] Metal is used for inside the valve of this product, when performing an inspection by MRI (Magnetic Resonance Imaging), note that the image may have artifacts and local high frequency heating.

<Use of stylet>

A stylet is attached to the catheter tube.

[1] Do not extend the catheter if it is broken or bent.
[The stylet may break when removed.]

[2] Make sure that the stylet is always attached to the tip of the catheter during insertion.
[The stylet may protrude from the side hole and damage the urethral mucosa.]

<Failures・Adverse events>

Failures

[1] Balloon burst
[Burst caused by the following causes.]
- Damage caused by the handling at the insertion (damage caused by forceps, scissors, knife or other apparatuses)
- Excess of the injection volume (injection of more than the specified volume)
- Injection of the wrong substance for balloon inflation (substances likely to coagulate easily such as isotonic sodium chloride solution or contrast media etc.)
- Damage due to the calculus in the patient.
- Sudden load on the product such as self (accidental) removal.
- Adhesion of the crystallized urine to the balloon.
- Other combined causes due to the above events

[2] Occlusion of the catheter.
[The lumen of the catheter may be occluded by the adhesion of the urinary constituents or blood clots etc.]

[3] Impossibility of the catheter removal.
[If the isotonic sodium chloride solution or contrast medium is used for the balloon inflation, the balloon lumen may be occluded due to the coagulation of the constituents and its removal from the balloon may become impossible.]

[4] Cut of the catheter.
[Cut due to the following causes]
- Damage caused by forceps, scissors, knife or other apparatuses
- Damage due to the calculus in the patient.
- Sudden load on the product such as self (accidental) removal.
- Excessive load on the product when peeling off the bandage etc. rapidly
- Other combined causes due to the above events.

[5] Breakage, bending, damage, or cutting of the stylet
[The stylet may be broken, bent, or cut due to the following causes]
- Insertion or removal with excessive force or operation with excessive torque
- Use with a kinked catheter
- Other combined causes due to the above events.

[6] Valve breakage / leakage.
[There is a possibility of valve breakage or leakage due to local high frequency heating.]

Adverse events

The following adverse events may be caused by the use of the product:
- Urinary tract infection.
- Bacillemia.
- Urinary tract injury
- Bladder calculus.
- Hematuria (hemorrhage)
- Pyrexia
- Pain
- Ulceration, perforation
- Leakage of the urine from catheter side.
- Urinary incontinence after removing the catheter.
- Urethral edema and ulcer around the catheter.
- Remains in the body due to catheter cutting

[Storage conditions and duration of use]

<Storage conditions>

Store the product hygienically, avoiding the direct sun light, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

< Expiration date >

See the expiration date given on each package provided that the device is stored appropriately.
[By self-authentication (our data).]

Manufacturer

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