

Tierrett Ureter Bypass Tube (Soft type)

Instructions for use

Contraindicated to re-use

[WARNINGS]

<Usage>

- [1] Make sure to adhere the fixing plate and catheter.
[Urine leaks due to catheter removal causes peritonitis.]
- [2] Make sure to adhere the fixing plate with the kidney or bladder.
[Urine leaks through the space causes peritonitis.]

[CONTRAINDICATIONS • PROHIBITION]

- Do not reuse the product (single use only).
- Do not use for patients with severe obstruction or disuse of the ureter.

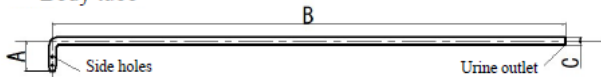
[Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

- Polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate) is used for the fixing plate.

<Shape>

<Body tube>



<Fixing plate>



Size	A: Tip length	B: Effective length	C: O.D.
8.5 Fr, For cats	35 mm	500 mm	φ 2.8 mm
8.5 Fr, For dogs	40 mm		
10 Fr, For cats	35 mm		φ 3.3 mm
10 Fr, For dogs	40 mm		

<Raw Materials>

- Body tube: Polyurethane
- Fixing plate: Polyester, Polyvinyl chloride

<Principles>

One of the catheter tubes is inserted into the renal pelvis and the other into the bladder to assist urination from the kidney to the bladder.

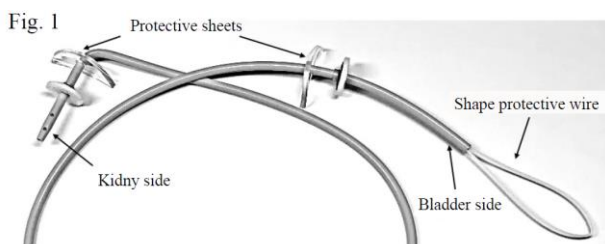
[Intended purpose, efficacy or effect]

Placed in the kidney and bladder to assist in urination from the kidney to the bladder.

[Operating or using method]

The below is a general procedure.

- [1] Pull out two sheets of the protective sheets and the shape protective wire and discard (Fig. 1).



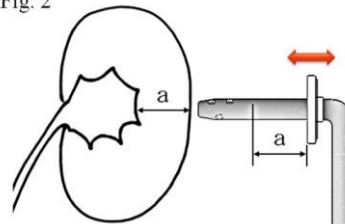
- [2] Shave and disinfect (clean, wipe) skin.

- [3] Open the abdominal by a midline abdominal incision. Wrap the entire gastrointestinal tract with a towel or etc. to expose only the target kidney.

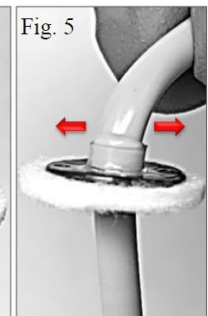
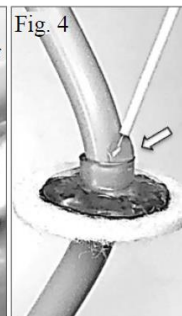
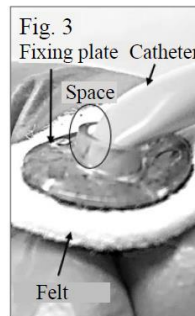
- Position determination of the fixing plate on the kidney side

- [4] The thickness (a) from the renal capsule to the renal pelvis in the central part of the kidney is measured by ultrasound (echo). Move the fixing plate to a position where the catheter side holes are placed in the renal pelvis to determine the fixation position (Fig. 2).

Fig. 2



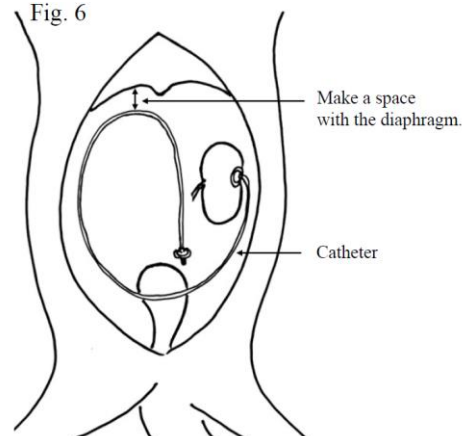
- [5] Bend the catheter at the fixation position to create a space between the fixing plate and the catheter (Fig. 3). Put medical instant glue between the space (Fig. 4). Move the catheter gently left and right or rotate the fixing plate (Fig. 5). Make sure that the glue is covered all over the space. After bonding, leave it two to three minutes to dry and check that it is fixed.



- Position determination of the fixing plate on the bladder side

- [6] Place the fixing plate on the bladder side the catheter with a gentle loop to a clockwise. If the catheter is long, cut the catheter end to adjust (Fig. 6). Place the fixing plate so that the catheter end is inserted into the bladder by approximately 1 cm.

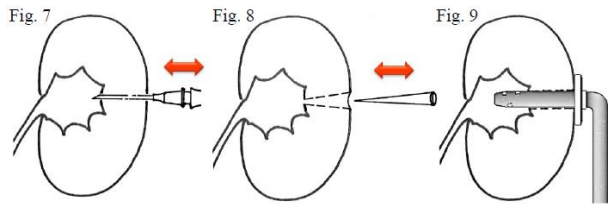
Fig. 6



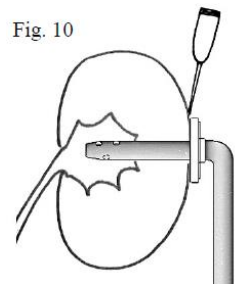
- [7] Fix the fixing plate on the bladder side of the catheter by gluing the space in the same way as in [5].

- Catheter placement on the kidney side

[8] While checking the renal pelvis by ultrasound (echo), insert a 18G indwelling needle from the central part of the kidney toward the renal pelvis until urine is slowly discharged (Fig. 7). Then, remove the indwelling needle. Dilate a catheter guide hole by re-inserting a micropipette through the hole where the indwelling needle was inserted (Fig. 8). Remove the micropipette. Insert the catheter tip on the kidney side into the renal pelvis (Fig. 9).

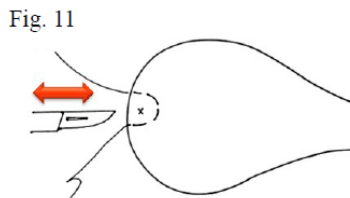


[9] While checking the position of the catheter in the renal pelvis by ultrasound (echo), inject an appropriate amount of saline from the bladder side of the catheter to check inflow into the renal pelvis. Also, check discharge from the bladder side of the catheter. Unless inflow or drainage can be confirmed, remove the catheter once and flush from the bladder side of the catheter to check clogging or etc. After re-insert the catheter into the renal pelvis to check inflow and drainage, glue the felt and the kidney (Fig. 10).



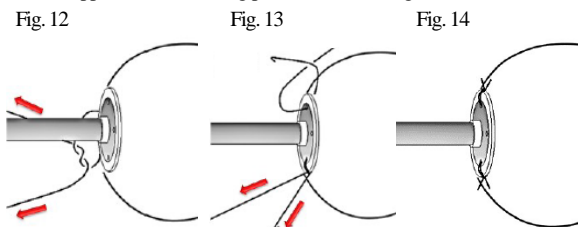
- Catheter placement on the bladder side

[10] Suture on the apex of the bladder by purse string suture and make a small incision in the center of the suture (Fig. 11).

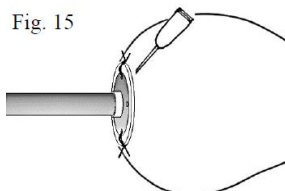


[11] Make a gentle loop of the entire catheter toward the bladder (Fig. 6).

[12] Insert the catheter end of the bladder side through the small incision. Ligate purse string suture with the felt of the fixing plate in contact with the serosal surface of the bladder (Fig. 12). Ligate and fix one of the fixing plate and the felt with using the suture (Fig. 13). Then, ligate and fix the bladder wall on the opposite side, the fixing plate, and the felt (Fig. 14).



[13] Glue the felt and the bladder wall (Fig. 15).



[14] Suture the abdominal wall and skin as usual to complete the surgery.

<Precautions for the using method>

- [1] The catheter loop must be loose and as large as possible with a space between it and the diaphragm.
[It risks catheter disconnection, kink, contact ulcer, etc. due to body movement.]

[Precautions]

Carefully apply to the following patients:

- [1] Check in advance if it is applicable to cases with renal stones.
[The tube may be blocked by stones.]

<Important basic caution>

- [1] Manage appropriately the catheter state during placement. Check the placement state as required.
[The catheter lumen may be occluded due to breakage, bending, twisting, urine components, stones, etc. of the catheter.]
- [2] Do not pinch the device with forceps too strongly.
[The tube may be cut, or the lumen may be occluded.]
- [3] Note that di (2-ethylhexyl) phthalate, which is a plasticizer for polyvinyl chloride, may elute in fat-soluble pharmaceuticals or chemicals.
[Polychlorinated vinyl chloride is used for the catheter.]

<Failures >

- [1] Occlusion of the catheter.
[The lumen of the catheter may be occluded by the adhesion of the urinary constituents or blood clots etc.]
- [2] Cut of the catheter.
[Cut due to the following causes]
 - Damage caused by forceps, scissors, knife or other apparatuses
 - Sudden load on the product such as self (accidental) removal.
 - Other combined causes due to the above events.
- [3] Catheter disconnection.
[Disconnection due to the following causes]
 - Unbonded, disconnection due to different glue filling position.
 - Sudden load on the product such as self (accidental) removal
 - Other combined causes due to the above events.

Adverse events

The following adverse events may be caused by the use of the product:

- Infection, bloodstream, fever, pain
- Kidney damage, ulceration, perforation, hematuria (bleeding), stones
- Urine leakage from the side of 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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In-house administration number: DC67965 R1-0 2021.7.21