Tierrett Ureteral Stent

Instructions for use

Contraindicated to re-use

[WARNINGS]

<Using method>

[1] When using this product, consider the urinary tract length of the patient before use and confirm that the pigtail part is not excessively formed. Also, consider using other tip shape types depending on the risk.
[There is a risk of knot at the tip of the renal pelvis during placement or removal.]

[2] After inserting the stent, make sure to confirm that the stent position is appropriate under fluoroscopy.

[3] The lumen of the stent tube may be blocked by urine components and stones etc.

[4] If resistance is felt during removal, check the cause of the resistance with X-rays and take appropriate measures.
[If it is forcibly removed, it may damage the renal pelvis and ureter.]

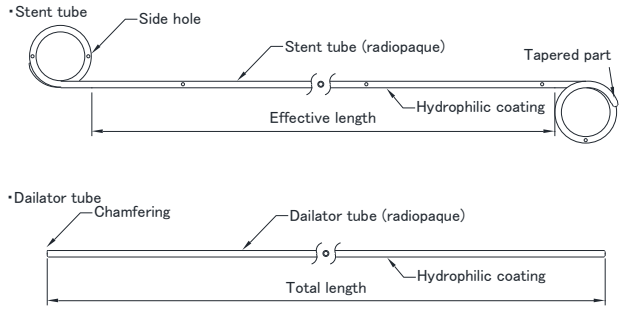
[CONTRAINDICATIONS・PROHIBITION]

Do not reuse the product (single use only).

[Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

<Shape>



Stent tube

Size	O.D.	I.D.	Effective length	Hydrophilic coating	Side hole
2.1Fr	0.71mm	0.45mm	80, 100, 120, 140, 160mm	Yes (surface only)	Yes
2.5Fr	0.83mm	0.53mm	120, 140, 160mm	Yes (surface only)	Yes

Dilator tube

Size	O.D.	I.D.	Total length	Hydrophilic coating
For 2.1Fr	0.73mm	0.53mm	300mm	Yes (surface only)
For 2.5Fr	0.86mm	0.53mm	300mm	Yes (surface only)

<Raw Materials>

・Stent tube: Polyurethane
・Dilator tube: Nylon
・Hydrophilic coating: Poly (methyl vinyl ether / maleic anhydride) copolymer

<Principles>

Inserted into the ureter and fixed and placed in a loop shape. Urine is drained through the surface and lumen.

[Intended purpose, efficacy or effect]

Inserted and placed in the ureter and used for drainage, drainage, cleaning, etc.

[Operating or using method]

The below is a general procedure.

<Placement method from the renal pelvis (antegrade)>

[1] Insert an indwelling needle from the surface of the kidney to the renal pelvis and insert the dilator tube to the distal side of the ureter while handling the tip of the outer tube.

[2] Insert the guidewire into the dilator tube and insert to the bladder. (For the guidewires recommended for this product, refer to the section <Medical devices used in combination>.)

[3] Pull out the dilator tube and insert the stent tube along the guidewire.

[4] Insert the dilator tube again along the guidewire, push one side of the stent tube into the bladder, then remove the dilator tube.

[5] Make an incision on the ventral side of the bladder, remove the guidewire from the incision slowly while holding the stent tube.

[6] Place the stent tube in place. Confirm that a loop has formed in the bladder and renal pelvis.

[7] The incision on the ventral side of the bladder is sutured and closed.

<Placement method from the bladder (retrograde)>

[1] Insert a guidewire into the stent tube and straighten the loops at both ends. (For the guidewires recommended for this product, refer to the section <Medical devices used in combination>.)

[2] Make an incision on the ventral side of the bladder, insert the set stent tube and guidewire through the urine outlet.

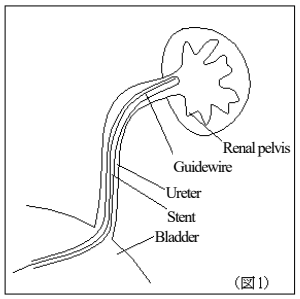
[3] Stop insertion when the tip of the stent tube reaches the renal pelvis. (Figure 1)

[4] While holding the guidewire, push the stent tube forward and confirm that the tip has looped in the renal pelvis. (Figure 2)

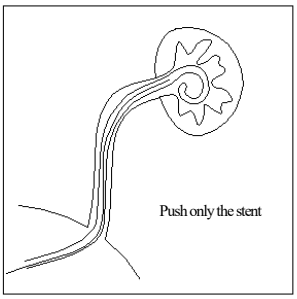
[5] Slowly remove the guidewire while supporting the end of the stent tube. (Figure. 3)

[6] Confirm that a loop is formed on the bladder side. (Figure. 4)

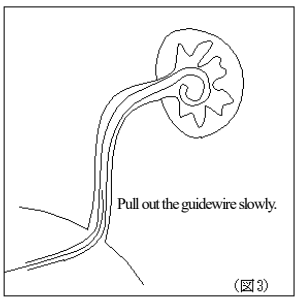
[7] The incision on the ventral side of the bladder is sutured and closed.



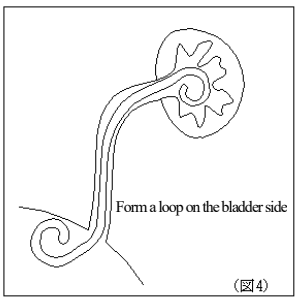
(Figure. 1)



(Figure. 2)



(Figure. 3)



(Figure. 4)

<Placement method from ureteral incision>

[1] Insert a guidewire into the stent tube and straighten the loops at both ends. (For the guidewires recommended for this product, refer to the section <Medical devices used in combination>.)

[2] Insert the set stent tube and guidewire from the ureteral incision toward the bladder side.

[3] Make an incision on the ventral side of the bladder, remove the guidewire from the incision slowly while holding the stent tube. At this time, the loop part should protrude from the ureteral incision part.

[4] Insert the guidewire again from the stent tube on the bladder side and straighten the loops at both ends.

[5] The stent tube and guidewire are pulled back into the urinary tract and then inserted into the renal pelvis.

[6] Stop insertion when the tip of the stent tube reaches the renal pelvis. (Figure 1)

[7] While holding the guidewire, push the stent tube forward and confirm that the tip has looped in the renal pelvis. (Figure 2)

[8] Slowly remove the guidewire while supporting the end of the stent tube. (Figure. 3)

[9] Confirm that a loop is formed on the bladder side. (Figure. 4)

[10] The incision on the ventral side of the bladder is sutured and closed.

<Removal method>

Grasp the end of the catheter from the bladder with forceps and gently pull out.

<Medical devices used in combination>

When using this product, use it in combination with the following medical devices.

Guidewire recommended for this product

Product name	O.D.	Total length	Adaptation
Tierrett Guidewire	0.41mm (0.016")	600mm or more	2.1Fr
	0.46mm (0.018")	600mm or more	2.5Fr

[Precautions]

<Important basic caution>

[1] Do not pinch the device with forceps too strongly.
[May cause broken stent tube and dilator tube, and occlusion of lumen.]

[2] When this product is used in cases with extreme stricture of the ureter, there is a risk of tissue and urethral mucosal damage.

[3] Do not immerse in chemicals containing organic solvents such as rubbing alcohol or wipe with chemicals.
[The stent tube and dilator tube may be damaged or cut, or the hydrophilic coating may be damaged.]

<Failures・Adverse events>

Failures

The following failures may be caused by the use of the product:

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

[2] Cut of stent tube and dilator tube.
[Cut due to the following causes]
・Damage caused by handling during insertion (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.
・Other combined causes due to the above events.

[3] Breakage, bending, damage, or cutting of the stent tube
[The stent tube may be broken, bent, or cut due to the following causes]
・Insertion or removal with excessive force or operation with excessive torque
・Other combined causes due to the above events.

Adverse events

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

・Fever
・Hematuria (bleeding)
・Pain
・Infection
・Bloodstream
・Pyelonephritis
・Renal dysfunction
・Ureter damage
・Frequent urination

[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: DC67878　R0-0　2020.11.2