

# Tierrett Guidewire

## Instructions for use

### Contraindicated to re-use

#### [WARNINGS]

##### <Using method>

- [1] After inserting the guide wire, make sure to check that the position is appropriate under fluoroscopy.  
[There is a possibility of damage to the renal pelvis and ureter, bending, damage, cutting, etc. of this product.]
- [2] If it felt resistance during operation, check the cause under fluoroscopy and take appropriate measures.  
[If operated forcibly, there is a possibility of damage to the renal pelvis and ureter, bending, breakage, and cutting of this product.]

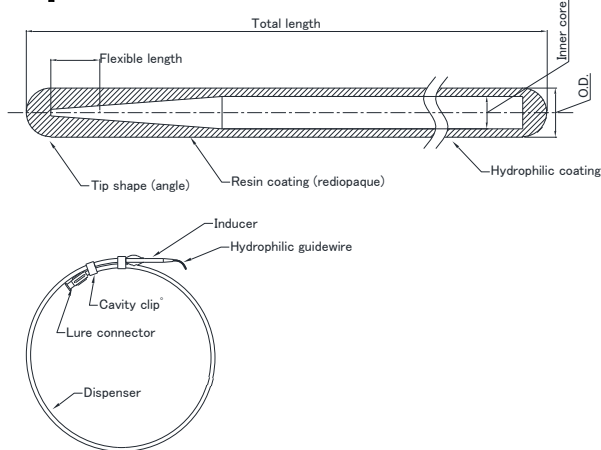
#### [CONTRAINDICATIONS • PROHIBITION]

Do not reuse the product (single use only).

#### [Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

##### <Shape>



#### Hydrophilic guidewire

Specification	Tip shape	O.D.	Total length	Flexible length
16-60-3T-MA-B	Angle	0.41mm (0.016")	60cm	3.0cm
18-60-3T-MA-B	Angle	0.46mm (0.018")	60cm	3.0cm

#### <Raw Materials>

- Hydrophilic guidewire
- Coating resin: Polyurethane
- Inner core: Ni-Ti alloy
- Hydrophilic coating:  
Poly (methyl vinyl ether / maleic anhydride) copolymer
- Dispenser: Polyethylene
- Cavity clip: Polyethylene
- Inducer: Modified polyphenylene oxide
- Lure connector: Polypropylene

#### <Principles>

The surface of this product has a hydrophilic coating, it shows lubricity after wetting. Inserted into the lumen of a stent etc. and urinary organs and placing the stent etc. along the product, it becomes easy to assist the position adjustment and movement of the stent etc.

#### [Intended purpose, efficacy or effect]

Temporarily used to assist the position adjustment and movement of stents to be inserted into the body. (Except for inserting into blood vessels and using)

#### [Operating or using method]

The below is a general procedure.

- [1] Remove the guidewire together with the dispenser from the packaging.
- [2] Fill the dispenser with saline or sterile distilled water from the luer connector using a syringe.
- [3] Remove the guide wire from the dispenser.
- [4] Check that the surface slips by touching with your fingers.
- [5] Fill with the lumen of a stent etc. to be used in advance by injecting saline or sterile distilled water.
- [6] Remove this product carefully after inserting into the body by referring to the package insert of the stent to be used.

#### <Precautions for the using method>

- [1] If the product cannot be removed from the dispenser, twist gently the dispenser to spread water over the entire surface of the product. If it still cannot take out, release the winding of the dispenser to some extent and take out.
- [2] Use with the surface wet.  
[If the surface is not wet, slipperiness cannot be maintained.]
- [3] If it felt a decrease in slipperiness, try to inject water.  
[If this product in a dry state is rubbed in a combined medical device, the hydrophilic coating may be peeled off.]
- [4] When holding this product, use gauze soaked in saline or sterile distilled water. Never use dry gauze.  
[The surface may be damaged and resistance may increase when reinserting into the combined medical device.]
- [5] Make sure to check under fluoroscopy during the procedure.  
[There is a risk of perforating and damaging the inside of the urinary tract with the tip of this product during the insertion procedure.]

#### [Precautions]

##### <Important basic caution>

- [1] Do not perform an inspection by MRI (Magnetic Resonance Imaging), with this product placed in the patient.  
[Due to the influence of the high-frequency electromagnetic field of MRI, the metal part may cause local high-frequency heating and cause burns to the patient.]
- [2] Do not pinch the device with forceps too strongly.  
[May cause broken guidewire.]
- [3] Do not use the guidewire and metal needle together.  
[Peeling of the hydrophilic coating layer, peeling of the coating resin, breakage and cutting may occur.]
- [4] Do not use metal torque devices.  
[May cause damage to the guidewire.]
- [5] When this product is used in cases with extreme stricture of the ureter, there is a risk of tissue and urethral mucosal damage.
- [6] When cleaning the surface of the guidewire, soak in a tray containing saline or sterile distilled water and rinse. If it is difficult to remove the dirt, wipe off gently with gauze soaked in saline or sterile distilled water. At this time, never rub strongly or wipe with dry gauze.  
[Hydrophilic coating may be damaged.]
- [7] Do not immerse in chemicals containing organic solvents such as rubbing alcohol or wipe with chemicals.  
[The guidewire may be damaged or cut, the hydrophilic coating may be damaged.]

#### <Failures • Adverse events>

##### Failures

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

##### [1] Reduced slipperiness

[The hydrophilic coating may be damaged due to the following causes and the slipperiness may decrease.]

- Use in a dry state.
- Operations such as unreasonable insertion and removal.
- Immersion or wiping with drug solution.
- Other combined causes due to the above events.

##### [2] Breakage, bending, damage, or cutting of the guidewire

[The guidewire may be broken, bent, or cut due to the following causes]

- Used in combination with metal needles and metal torque devices.
- Insertion or removal with excessive force or operation with excessive torque.
- Use for kinked stents, etc.
- Other combined causes due to the above events.

##### [3] Impossibility of the guidewire removal.

[May become impossible to remove due to the following causes.]

- Breakage, bending, damage, or cutting of the guidewire.
- Reduced slipperiness.
- Excessive insertion into the ureter.
- Use for kinked stents, etc.
- Other combined causes due to the above events.

##### [4] Damage to stents etc.

[Stents etc. may be damaged due to the following causes.]

- Insertion or removal with excessive force or operation with excessive torque.
- Breakage, bending, damage, or cutting of the guidewire.
- Reduced slipperiness.
- 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 (perforation)
- 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).]

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