# Instructions for use

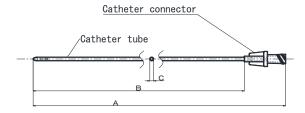
# Contraindicated to re-use

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

## [Shape, structure, principle]

This product is sterilized with ethylene oxide gas.

#### <Shape>



Size	A: Total length	B: Effective length	C: O.D.
8Fr	400mm	370mm	2.7mm
10Fr	400mm	370mm	3.3mm
8Fr (Long type)	580mm	550mm	2.7mm
10Fr (Long type)	580mm	550mm	3.3mm

## <Raw Materials>

Catheter: PVC (polyvinyl chloride)

## <Principles>

Insert the catheter into the bladder. Urine is discharged from the side hole through the lumen and through the urine outlet.

# [Intended purpose, efficacy or effect]

Placed in the bladder and used for urinary catheterization.

## [Operating or using method]

The below is a general procedure.

- [1] Disinfect (clean, wipe) the external urethral meatus and vulva as required.
- [2] Remove the product from the packaging material hygienically and insert into the urethra and bladder.
- [3] 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
- [4] After confirming the drainage, advance about 2 cm further and connect the urine outlet of the catheter to a urine bag etc. as required.
- [5] When removing the catheter, remove the urine bag etc. connected to the catheter, after release the catheter, pull out slowly and gently.

#### <Precautions for the using method>

[1] When connecting a urine bag etc. to the catheter urine outlet, make sure to

select one fits. Check for leaks and looseness at the connections during use, make sure to use it in a connected state.

#### [Precautions]

#### Carefully apply to the following patients;

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] 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.]
  - [There is a risk of ulceration, perforation, etc. when the tip of the catheter comes in contact with the bladder wall.]
- [2] Do not pinch the device with forceps too strongly.
- [The tube may be broken or 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 connection 2 port adapter.]

#### <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
  - 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.

# Adverse events

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

- · Urethral infection, bloodstream, fever, pain
- · Urethral damage, ulceration, perforation, hematuria (bleeding), bladder stones
- · Urine leakage from the side of the catheter, urinary incontinence after removal
- 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).]

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