

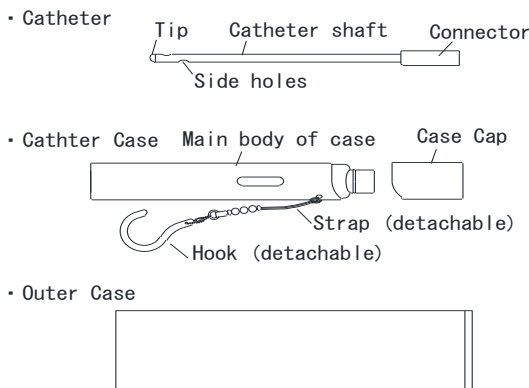
**[Warning]**  
 This device must be used after it has been disinfected using an appropriate antiseptic solution of right concentration.  
 [It is a non sterilized product.]

**[Contraindications / Prohibitions]**

- Do not use in patients with urethral stenosis.  
 [Otherwise, it may damage tissues and/or urethral mucosa.]
- Do not resort to sterilization and/or boiling to the catheter case, cap and outer case.  
 [Otherwise, it may deform the device and impair the intended function.]
- This device is intended for the use in women, and should not be used in men because the length is too short.  
 [The length of the portion of this device inserted into the patient body is approx. 110 mm.]
- In case that insertion of this catheter could not allow the patient to urinate, do not use the device.  
 [For some patients, the length of this catheter may be too short. In addition, patient's urine may not run through the catheter due to the urine condition.]
- Do not use any other catheter to apply in the case of this product than the one that is preset.  
 [Otherwise, it may lead to a difficulty to close the case cap or to take out the catheter.]
- After opening the package, the device must be replaced when it passed the shelf life. Do not keep using the catheter unit or the case together with other new components.  
 [Otherwise, the catheter may be degraded and result in breaking and/or urination disability.]  
 [Otherwise, the case may be degraded and result in leakage and/or breakage.]

**[Shape, Structure, and Brief Description on the Usage, etc.]**

**<Shape>**



**<Material>**

Silicone rubber

**<Dimensions>**

- Catheter

Size	Outer diameter	Total length	Feature
9 Fr	3.0 mm	125mm	2 side holes
12 Fr	4.0 mm		
12Fr Hard Type	4.0mm		
14 Fr	4.7 mm		

**<Principals>**

Take out the catheter from the case filled with antiseptic solution, and perform self catheterization. After each self catheterization, the used catheter can be cleaned and housed in the case for the purpose of storage and carrying around.

**[Intended Usage]**

The device is to be inserted temporarily into the urethra, bladder, or drainage port after urinary diversion surgery to be used for urination.

**[Effect]**

Can be inserted into the urethra, bladder, or drainage port after urinary diversion surgery and lead to temporary urination.

**[Performance]**

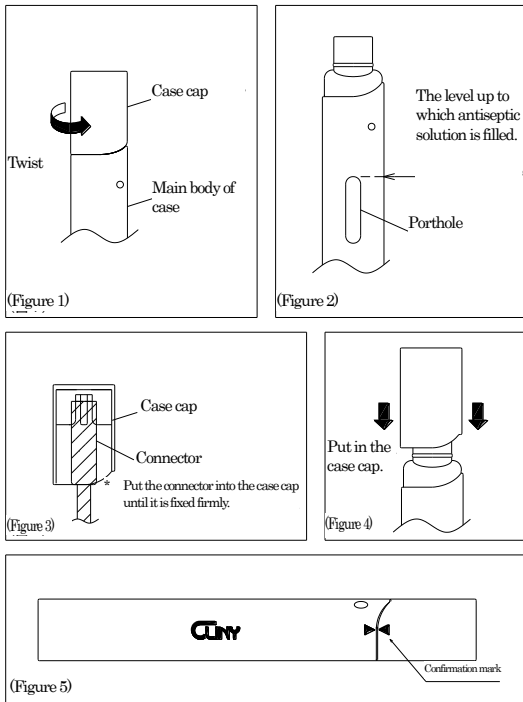
- Do not contain materials of biological origin and be compatible with biological safety.
- Can withstand 29 days of reuse.
- To be stable and durable for 5 years.
- It doesn't cut when stretching both ends of this product with the following load in the length direction.  
 O.D. 2-4mm : 10N, O.D. ≥4mm : 20N

**[Operation Procedure]**

A typical operation procedure is described below:

**<How to prepare>**

- 1) Twist and open the case cap (Figure 1) to take out the catheter. (The fit of the case cap and the main body of case is designed for the occasions in which they are wet with antiseptic solution. It might be rather tight just after the first opening.)
- 2) Fill the main body of case with an antiseptic solution of right concentration. The solution should be poured into the main body of case to the level just above the porthole of the case (approx. 5.5 mL) (Figure 2).
- 3) Put the connector of the catheter into the inside of the case cap (Figure 3).
- 4) Insert the catheter into the main body of case. Put in the head of the case cap on the main body of case until it clicks (Figure 4), and see the confirmation mark to make sure that the main body of case and the case cap fit completely. (Figure 5)
- 5) Wipe off the moisture on the surface of the case.



#### <How to perform self catheterization (instructions to be given to patient)>

- 1) Wash hands, or clean hands with towelette or purity cotton.
- 2) Pull down garment and underpants, and take an appropriate posture to drain urine.
- 3) Widen vulva in one hand, and wipe urethral orifice from anterior to posterior using another hand with a purity cotton.
- 4) Twist and open the case cap to take out the catheter.
- 5) With the case hook, hang the main body of case from an appropriate position (e.g. the doorknob inside the bathroom, the axis of the bathroom paper holder).
- 6) When needed, apply a lubricant agent to the tip of the catheter.
- 7) Widen vulva in one hand, take the catheter using another hand in a way like when holding a pencil, and insert it to urethral orifice. Be sure to take off the case cap beforehand.
- 8) After draining urine, pull the catheter slowly, and take it out from body when urine is drained completely.
- 9) After use, clean the catheter with tap water, and house and store it within the case according to the steps 3) to 5) of <How to prepare>.

#### <Precautions related to the operation procedure>



- 1) Do not open or close of the case cap / the main body of case forcibly. Do them slowly referring to Figures 1 and 4.
- 2) If an antiseptic solution is poured into the main body of case when it is tilted, or if the catheter is put into the main body of case in which antiseptic solution is filled too much, the antiseptic solution may spill out. In case the antiseptic solution spilled out, wipe off the moisture on the main body of case and the case cap before their storage.  
[If the antiseptic solution is not wiped off completely, the residual antiseptic solution might seep through the bottom of the main body of case, as if there is a leakage of antiseptic solution.]

- 3) Do not rub the main body of case, case cap, strap, and/or hook too strongly when wiping off the antiseptic solution on them. Do not wipe off this product using alcohol for disinfection.  
[Otherwise, the printing made on the case may be erased or the device may have a crack or tear.]
- 4) When put the connector of the catheter into the inside of the case cap, push the connector until it is fixed firmly.
- 5) After closing the case cap, make sure that the main body of case and the case cap fit completely, and that antiseptic solution does not leak from the case. (See Figure 5 in <How to prepare>.)  
[If the main body of case and the case cap do not fit completely, antiseptic solution may leak.]
- 6) Do not pull the hook or the strap strongly or apply excessive load.  
[The hook and the strap are only for the use of hanging the main body of case during urine drainage.]
- 7) When hanging the main body of case with the hook, choose the position where the hook can be placed firmly, and release hand after it becomes stable.  
[Otherwise, antiseptic solution may spill out and/or the main body of case may fall and result in breakage.]
- 8) If a patient could not insert catheter into her(user) urethral orifice appropriately, tell her not to insert it forcibly but to insert it slowly in a relaxed state, breathing deeply. (Insertion may be easier when a patient has an image that her urethra is opening by itself.)
- 9) When the catheter is inserted with the case cap being attached, urine will leak from the case cap. (The case cap does not seal off the catheter completely.)

#### [Precautions]

##### <Important general instructions >

- 1) Before using this product, please provide right instructions to the patient. Especially, for a disabled person, child, the elderly, or the others who cannot perform opening/closing of the case and/or catheter insertion appropriately, explain and give instructions in a careful and understandable manner. In addition, make the patient's family member(s) and/or caretaker(s) have a good understanding to ensure their cooperation and assistance.
- 2) Do not wipe off this product using alcohol for disinfection.  
[Otherwise, the printing made on the case may be erased or the device may have a crack or tear.]
- 3) If the device does not function as a catheter for self catheterization due to the reasons such as clogging or contamination caused by aging, it should be replaced with a new device for self catheterization even if it is within the shelf life, based on the physician's judgment.
- 4) Before using this product, check every component for any abnormalities.
- 5) Do not insert the catheter forcibly. If there is difficulty in insertion, stop the use. Do not pull or bend the catheter forcibly.  
[Otherwise, it may harm the patient's tissues.]  
[Otherwise, it may cause damage of the product.]
- 6) If there is any abnormality, stop the use immediately and take appropriate measures.
- 7) Do not modify the product.  
[If any feature (e.g. side hole(s)) is added, it may cause breakage of the catheter.]
- 8) Do not expose this product to an organic solvent, strong acid, strong base, or any equivalent agent.
- 9) Do not hold this product strongly with forceps or other tools.  
[Otherwise, it may cause a tear of the catheter or clogging in the lumen.]

- 10) In case of any abnormality including damage in the package or the device, do not use the product.
- 11) Use the product soon after the package is opened and dispose the used product in a secure manner for each country.
- 12) When  is found on the label, it means that the product should not be used if the package has been damaged or opened.
- 13) When  is found on the label, it means the product Doesn't contain DEHP in the contact part with body fluid and drug solution.
- 14) Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

#### <Failures>

By using this product, the following failures might occur:

- If the device is not cleaned or disinfected appropriately, the lumen of the catheter may be clogged, or catheter may be colored or degraded.
- If opening or closing the main body of case / the case cap is done forcibly, it may result in a breakage of the case.
- If the product is fallen or hit while it is carried or stored, it may result in a breakage of the case or a release of the strap. Also, the case cap may be loosened and antiseptic solution may leak out.
- If the main body of case and/or the case cap are kept without completely wiping off the moisture on them, decoloration may occur.
- If the main body of case, case cap, strap, and/or hook is rubbed too strongly when wiping off the antiseptic solution on them, it may result in a paint detachment or breakage.

#### <Adverse events>

By using this product, the following adverse events may occur:

- Urethralgia or distress during catheter insertion at initial period of self catheterization.
- Urinary tract infection such as cystitis or pyelonephritis.  
[In the case of having a small urinary volume every day or a difficulty in keeping herself clean.]
- Urethral injury, hemorrhage.
- Leakage of antiseptic solution. (If the main body of case and the case cap do not fit completely, it is easier to result in a leakage of antiseptic solution especially while being on board the flight due to changes in atmospheric pressure.)

#### **[Method of Storage and Shelf Life]**

##### <Method of storage>

This product must be stored under clean conditions and prevented from direct sunlight, high temperature and humidity, low temperature below 10°C, and ultraviolet ray including a sterilamp.

##### <Duration of use>

This product is recommended to be replaced with a new device within 1 month.

[Self-certification (based on in-house data).]

##### <Expiration date>

- See the expiration date given on each package provided that the device is stored appropriately.  
[Self-certification (based on in-house data).]
- Store the device carefully and never use the device after the expiration date.

#### **【The matters pertaining to the maintenance and inspection】**

##### <Maintenance and inspection items by the user>

- 1) Prescribe an appropriate antiseptic solution of right concentration

for the patient. Below provides the drug names and the reference concentration for use, for information. However, the concentration must be decided considering the patient conditions based on the physician's experiences.

General name	Reference concentration for use	Usage experience
sodium hypochlorite	0.0125~0.02%	Dilute "Milton" 50 to 80 times with water.

General name	Reference concentration for use
Benzalkonium chloride solution	0.05 ~0.1%
Benzethonium chloride solution	0.05 ~0.1%

Note) The device may be colored depending on the disinfectant used.

- 2) It is recommended to exchange antiseptic solution once daily. If the device is not used for long time, dry it completely before storage. In such cases, do not use the device after it passed the shelf life after opening.



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