Self-Catheterization Set

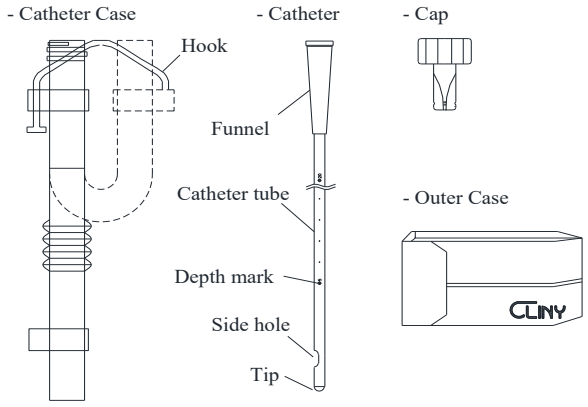
Self-Catheterization Set
Self-Catheter

[WARNINGS]
The product must be used after it has been disinfected using an appropriate disinfectant of right concentration.
[The product is a non-sterilized.]

[CONTRAINDICATIONS/PROHIBITIONS]
- Do not use the catheters other than Tieman Type for any case with urethral stenosis.
  [It may harm the patient's tissues as well as urethral mucous membrane.]
- Do not sterilize and/or boil the Catheter case.
  [Otherwise, it may deform the product and impair the intended function.]

[SHAPE, STRUCTURE AND PRINCIPLE]

<Shape>



* The Catheter case, Cap and External case are not provided for Self Catheter.

< Raw materials >
Silicone Rubber

<Specifications>

Type	Catheter			
	Size	Outer diameter	Total Length	Shape
Female Type	10Fr	3.3mm	165mm	1～4 side hole(s)
	12Fr	4.0mm		
	14Fr	4.7mm		
	16Fr	5.3mm		
Male Type	10Fr	3.3mm	300mm	1～4 side hole(s)
	12Fr	4.0mm		
	14Fr	4.7mm		
	16Fr	5.3mm		
Male-L Type	10Fr	3.3mm	350～395mm	1～4 side hole(s)
	12Fr	4.0mm		
	14Fr	4.7mm		
	16Fr	5.3mm		
	18Fr	6.0mm		
	20Fr	6.7mm		
Pediatric Type	9Fr	3.0mm	265mm	1 side hole
Tieman Type	12Fr	4.0mm	300mm	1 side hole Tieman tip
	14Fr	4.7mm		

Type	Catheter			
	Size	Outer diameter	Total Length	Shape
C.U.R. Type	14Fr	4.7mm	395mm	5 side holes
	16Fr	5.3mm		
	18Fr	6.0mm		
	20Fr	6.7mm		

Type	Catheter		External case
	Size	Depth mark	Measurement
Female Type	10Fr	Depth marks at 10mm intervals between 10mm to 100mm from the tip	60×117×15mm
	12Fr		
	14Fr		
	16Fr		
Male Type	10Fr	Depth marks at 10mm intervals between 50mm to 200mm from the tip.	60×190×15mm
	12Fr		
	14Fr		
	16Fr		
Male-L Type	10Fr	Depth marks at 10mm intervals between 50mm to 250mm from the tip.	60×232×15mm
	12Fr		
	14Fr		
	16Fr		
	18Fr		
	20Fr		
Pediatric Type	9Fr	Depth marks at 10mm intervals between 10mm to 200mm from the tip.	60×190×15mm
Tieman Type	12Fr	Depth marks at 10mm intervals between 50mm to 200mm from the tip.	60×190×15mm
	14Fr		
C.U.R. Type	14Fr	Depth marks at 10mm intervals between 100mm to 250mm from the tip.	60×232×15mm
	16Fr		
	18Fr		
	20Fr		

Note) C.U.R. : Continent Urinary Reservoir
(Special catheter for substitutional urinary bladder)

<Principle>
Take out the catheter from the case filled with disinfectant 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.
Also, it is possible to fold the case when carrying around.

[INTENDED USE]
The product is to be inserted into the patient's urethra, bladder, or drainage port temporally after urinary diversion surgery to be used for urination.

[EFFICACY OR EFFECT]
The product is to be inserted into the patient's urethra, bladder, or drainage port after urinary diversion surgery, and can be used for temporary urination.

[PERFORMANCE]
- Do not contain materials of biological origin and be compatible with biological safety.
- Can withstand reuse for 29 days.
- To be stable and durable for 5 years.

・It doesn't cut when stretching both ends of the product with the following load in the length direction.
O.D. 2-4mm：10N, O.D.≧4mm：20N

[OPERATING AND USING METHOD]

The general operational procedure is described below.

1) Straighten the catheter case and fill the catheter case with a disinfectant of right concentration. See the following drawing as target amount of solution (Figure 1).

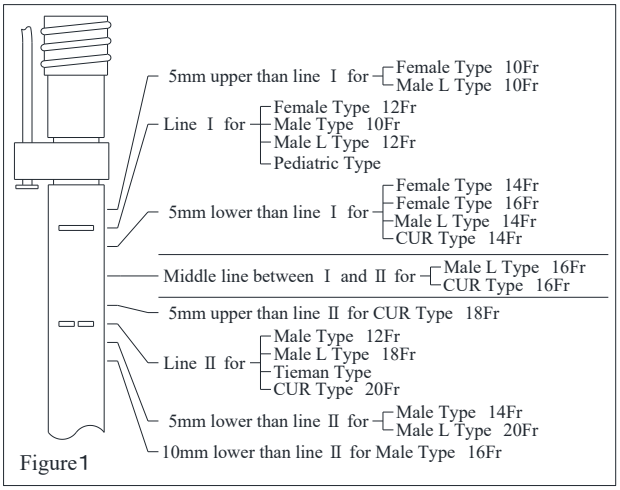


Figure1

2) Push the cap into the funnel until the chase of the cap places at the second lib of the funnel in order to fix firmly. (Figure 2).

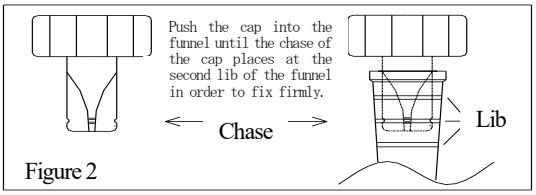
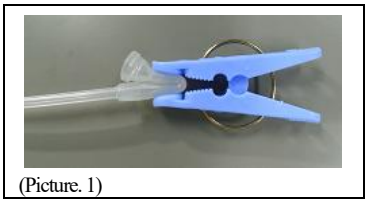


Figure 2

3) Straighten the catheter case and insert the catheter with cap into the catheter case. Turn the cap surely and lock it in firmly. And make sure that disinfectant is not leaked from the catheter case.
4) Pull out the catheter and take urination procedure.
5) After use, clean the catheter with tap water. And then, house and store it into the catheter case in accordance with the steps 2) to 3).
6) After folding the catheter case and keeping the folded form by hook, put it in the External case.

<Precautions in use related with the method of use>

1) When attaching the cap into the funnel of catheter, insert the cap to the specific position (See figure 2). In addition, when closing the catheter case and cap, be sure to turn the cap securely to fix it firmly.
[Leakage of disinfectant may occur]
2) Insert the catheter into body after uncapping. Attach the cap to the case and screw it lightly or put it at clean place.
3) When it is difficult for patients to insert the catheter into the urethral opening, instruct the patients not to insert the catheter forcibly and to insert it slowly while relaxing and taking a deep breath. (The insertion may be easier, if the patients imagine opening the urethra by themselves.)
4) Bend the funnel of the catheter and pinch the part with clothespin or the like when stopping flow of urine at the insertion (See image 1). Do not use clothespin with sharp edge or do not pull the clothespin when detaching it.
[It may cause breakage of the product or obstruction of the lumen.]


(Picture. 1)

[PRECAUTIONS IN USE]

<Important basic precautions>

1) Before using the product, 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 them 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) Before using the product, check whether there is any abnormality in each part.
3) Do not insert and withdraw the catheter forcibly. If there is difficulty in insertion, stop the use. Do not pull or bend the catheter forcibly when using it.
[Otherwise, it may harm the patient's tissues.]
[Otherwise, it may cause breakage of the product.]
4) If there is any abnormality, stop the use immediately and take appropriate measures.
5) Do not modify the product.
[If a side hole, etc. is added, the catheter may be cut.]
6) Do not expose the product to an organic solvent, strong acid, strong base, or any equivalent agent.
7) Do not grip the product strongly with forceps, etc.
[Otherwise, it may cause a tear of the catheter or obstruction in the lumen.]
8) Do not use if the packaging is damaged or if any abnormality such as damage is found in the product.
9) Use the product appropriately after opening and dispose it in a safe manner for each country after replacing with a new product.
10) printed on the label means that the product should not be used if the package is damaged or opened.
11) printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.
12) Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

<Defects>

By using the product, the following defects might occur:

・If the product is not cleaned or disinfected appropriately, the lumen of the catheter may be obstructed, colored, or degraded.
・If the main body of catheter case and the cap are attached or detached 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 hook. Also, the case cap may be loosened and disinfectant may leak out.

<Adverse events>

・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 /himself clean.]
・False passage (In case of male)
[Forcible catheter insertion]

・Leakage of disinfectant.

[STORAGE METHOD AND DURATION OF USE]

<Storage method>

Store the product cleanly. Avoid direct sunlight, high temperature and humidity, low temperature below 10℃ and ultraviolet rays such as germicidal lamp, etc.

<Duration of use>

The product is recommended to be replaced with a new device within 29 days.
[Self-Certification (based on in-house data).]

<Expiration date>

- When the proper storage method has been maintained, refer to the expiration date on the individual package.
  [Self-Certification (based on in-house data).]
- Store the product with great care, and do not use if it passed the expiration date

【Items on maintenance and inspection】

<Items for maintenance and inspection by users>

1) Prescribe an appropriate disinfectant of right concentration for the patient. Drug names and the reference concentration for use are provided below for information. However, the concentration must be decided considering the patient conditions based on the physician's experiences.

Generic name	Reference concentration for use	Example of use
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 product may be colored depending on the disinfectant used.

2) It is recommended to exchange disinfectant once daily. If the product is not used for long time, dry it completely before storage. In such cases, do not use the product after it passed the duration of use after opening. If the product is not used for a long period of time, do not bend the case and store it straight.

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